United States Department of Agriculture
Food Safety and Inspection Service
Washington, D.C. 20250

Dr. Romano Marabelli
General Director
Department of Food and Nutrition and
Public Veterinary Health
Ministry of Health
Piazza Marconi, 20-00144
Rome, Italy

NOV 19 2001

Dear Dr. Marabelli:

We have received your comments pertaining to the May 7 through June 6, 2001, Food Safety and Inspection Service (FSIS) audit of Italy's meat inspection system. Enclosed is a copy of the final audit report. Italy's comments have been included as Attachment G to the final report.

In the July 20, 2001,letter from Dr. John C. Prucha, FSIS requested that the Government of Italy (GOI) respond specifically as to how it planned to (1) reverse the decline in central and regional government supervision of local inspection activities in U.S.-certified meat establishments, (2) correct present and prevent future sanitation deficiencies in these establishments, and (3) restore FSIS' confidence that meat product from Italy meet the U.S. Appropriate Level of Protection.

FSIS appreciates your thoughtful responses to the findings outlined in our draft final report and accompanying letter. We also appreciate actions taken to correct deficiencies identified in the audit. While I understand that you may not fully agree with some of the conclusions FSIS has drawn from our last three audits of Italy's meat inspection system, we respectfully continue our belief that recent audit results demonstrate serious problems with GOI supervision of meat establishments certified for export to the U.S.

We are encouraged, however, by several activities being undertaken by the GOI to improve its meat inspection system with respect to those establishments certified to export to the U.S. For example, you have formed a working group from the Ministry of Health to standardize inspection requirements across regions and to develop standardized reporting and record keeping forms and reports. You note that training in Pathogen Reduction/Hazard Analysis and Critical Control Point requirements has been provided to several establishments and government inspection officials. You note that the GOI has placed particular emphasis on supervision of certified establishments and the proper implementation of Sanitation Standard Operating Procedures and Hazard Analysis and Critical Control Point Systems (HACCP) in certified establishments. Lastly, you note that the veterinary staff at the headquarters of the Ministry of Health has been increased, and the additional resources will be used to supervise

inspection activities in certified establishments. Our auditors will be focusing in particular on activities undertaken by the Ministry of Health headquarters and regional officials to improve government supervision of local inspection activities in establishments certified for export to the U.S.

I would like to make a few general comments about your response to our draft audit report. First, I want to make it clear that FSIS uses a standard approach to all of its audits of foreign inspection systems. These standards do not change depending on what country is being audited. These standards also do not change when the auditor changes. FSIS carries out U.S. obligations under the EU/US Veterinary Equivalence Agreement by conducting its audits of European Community (EC) Member States using EC meat or poultry inspection requirements as the standard for equivalence.

There are, however, two exceptions to this general rule. One is for FSIS Pathogen Reduction and HACCP requirements. The other exception pertains to overarching FSIS import requirements set forth in the U.S. Code of Federal Regulations at Part 327 for meat and Part 381 for poultry. Electronic copies are available at the sites listed below.

For meat: http://www/access/gpo.gov/nara/cfr/waisidx_00/0cfr327_00.html

For poultry: http://www.access.gpo.gov/nara/cfr/waisidx_00/9cfr381_00.html

Our position is that if a specific FSIS import requirement is appropriately addressed in an EC Directive or other Community issuance and has been properly transposed by a Member State, then FSIS will defer to the Member State's requirement and will audit against it to verify continuing equivalence. It is important to note that the U.S. Code of Federal Regulations sets import requirements that carry the force of United States law and FSIS is required to enforce them.

An example of an overarching U.S. import requirement is the mandate that continuous daily inspection coverage be provided in all certified establishments. In meat processing establishments, daily inspection may be performed by a competent government inspector who is not a veterinarian. There is no provision under U.S. import regulations for daily inspection presence to be waived. Consequently, FSIS must continue to audit against the U.S. requirement for daily inspection coverage in all establishments certified by the GOI for export to the United States.

Another example of an overarching U.S. import requirement is the mandate for monthly supervisory visits by a representative of the foreign inspection system not less frequently than one such visit per month to each certified establishment. This requirement is explicitly for a supervisory visit each month to verify that the local government inspection staff who are in the establishment every day are properly executing their inspection duties. As such, the visit should be conducted by a representative from an organizational level higher than the local veterinarian. We are willing to consider an alternative means of complying with this U.S.

import requirement, but we cannot waive it. The alternative you propose must include monthly visits by an official who is not a member of the government staff that conducts daily inspections in the establishment.

Comments on the On-Site Audits of Establishments

We have reviewed corrective actions taken by the GOI and the individual establishments set forth in your letter for establishments 92M/S; 272M/S; 643M/S; 989L; and 1597L. We find the written corrective actions to be satisfactory in these establishments. (The remaining establishments that were delisted in May 2001 remain delisted and may not export product to the U.S. until they have been re-audited on-site by FSIS.) We note that the GOI has re-certified these five establishments as eligible to export to the U.S. In other words, the GOI has determined that these establishments have addressed and corrected all the deficiencies noted during the May 2001 audit, and now meet all EC and U.S. inspection standards and requirements. In our November 2001 follow-up audit, our auditors will be verifying that the corrective actions were indeed taken in each of these previously-delisted establishments.

During this current audit, we will be continuing the certification policy outlined in our July letter from Dr. Prucha. Any establishment that is rated unacceptable during this audit may not be re-certified for export by the GOI until FSIS or EC auditors revisit the facility and verify that it is complying with all applicable EU and U.S. requirements. For your information, each of the establishments that were rated unacceptable and all of the establishments rated acceptable/re-review during the May 2001 audit will be rated as either acceptable or unacceptable during the current audit. There will not be an acceptable/re-review category for these establishments.

Comments on the On-Site Audits of Laboratories

With respect to GOI responses concerning our audits of laboratories, we continue to have concerns as set forth in the following paragraphs.

Food Microbiology Laboratory (Rome) and Food Microbiology Laboratory (Florence)

Our auditor found that these laboratories were modifying the standard ISO Method #11290-1 for *Listeria monocytogenes*. This is not acceptable. Any modification to an accepted method of testing must be reviewed by FSIS before the method can be modified. These laboratories must use the standard ISO Method without modification until an equivalence request is received and reviewed by the International Policy Staff.

Our auditor also found that these laboratories were using the Biomerieux "Coli-ID" method of analysis for *Escherichia coli (E. coli)*. In documents submitted to FSIS, the GOI stated that Italy was adopting the FSIS requirements for generic *E. coli* testing. As such, the GOI laboratories should be using one of the *E. coli* (Biotype1) quantification methods found the in the Official Methods of Analysis of the Association of Official Analytical Chemists, International, 16th edition, or by any method which is validated by a scientific body in collaborative trials against the three tube Most Probable Number (MPN) method and agreeing

with the 95% upper and lower confidence limits of the appropriate MPN index. Any use of a different method of analysis must be reviewed by the International Policy Staff before the new method may be used. In the meantime, Italy's microbiology laboratories that test product intended for export to the U.S. must use one of the methods identified above to analyze for generic *E. coli.*

In addition, the laboratories check sample program did not meet FSIS requirements. FSIS requires that check samples for *Salmonella* and *Listeria monocytogenes* be tested three times each year. Check samples for these organisms were lasted tested in 1999.

Food Microbiology Laboratories of Ancona and Perugia

Our auditor found that these laboratories were not adhering to a single standard method of analysis for *Salmonella.* In comments from the GOI, it was stated that two screening methods are used. FSIS requests a copy of the validation study done by AFNOR.

Our auditor found that these laboratories were modifying the standard ISO Method #11290-1 for *Listeria monocytogenes.* This is not acceptable. Any modification to an accepted method of testing must be reviewed by FSIS before the method can be modified. These laboratories must use the standard ISO Method without modification until an equivalence request is received and reviewed by the International Policy Staff.

Our auditor also found that these laboratories were using the Biomerieux "Coli-ID" method of analysis for *Escherichia coli (E. coli).* In documents submitted to FSIS, the GOI stated that Italy was adopting the FSIS requirements for generic *E. coli* testing. As such, the GOI laboratories should be using one of the *E. coli* (Biotype1) quantification methods found the in the Official Methods of Analysis of the Association of Official Analytical Chemists, International, 16th edition, or by any method which is validated by a scientific body in collaborative trials against the three tube Most Probable Number (MPN) method and agreeing with the 95% upper and lower confidence limits of the appropriate MPN index. Any use of a different method of analysis must be reviewed by the International Policy Staff before the new method may be used. In the meantime, Italy's microbiology laboratories that test product intended for export to the U.S. must use one of the methods identified above to analyze for generic *E. coli.*

In addition, the check sample program in these laboratories did not meet FSIS requirements. FSIS requires that check samples for *Salmonella* and *Listeria* be tested three times each year. Check samples for these organisms were lasted tested in 1999.

Food Microbiology Laboratory of Brescia and Food Control Laboratory of Turin

Our auditor found that these laboratories were modifying the standard ISO Methods for *Salmonella* and *Listeria monocytogenes.* This is not acceptable. Any modification to an accepted method of testing must be reviewed by FSIS before the method can be modified.

These laboratories must use the standard ISO Method without modification until an equivalence request is received and reviewed by the International Policy Staff.
In addition, the check sample program at these laboratories did not meet FSIS requirements. FSIS requires that check samples for *Salmonella* and *Listeria* be tested three times each year. Check samples for these organisms were lasted tested in 1999.

As you know, the FSIS follow-up audit of Italy's meat inspection system began on November 14. This is a three-person audit. Two auditors will be auditing individual establishments, including those establishments that were delisted and subsequently relisted for export and those establishment that were determined to be acceptable subject to a re-audit. The third auditor will audit a sample of Italy's microbiology laboratories and will review activities that have been undertaken by the GOI to correct inspection deficiencies noted in the May 2001 (and previous) audits and will examine supporting documentation of these activities by the national, regional and local authorities.

If you have any questions regarding this letter or the upcoming audit, please contact me at 202-720-3781. My facsimile number is 202-690-4040 and my email address is sally.stratmoen@usda.gov.

Sincerely,

Sally Stratmoen

Sally Stratmoen
Acting Director
International Policy Staff

Enclosure

cc:
Alejandro Checchi-Lang, European Commission, Brussels, Belgium
Elizabeth Berry, Counselor, U.S. Embassy, Rome
Ruggero Corrias, Second Secretary, Embassy of Italy, Washington, DC
Mary Revelt, Minister/Counselor for Agr Affairs, USEU/Brussels
Gerry Keily, Counselor (Agriculture), EU Mission to the US, Wash DC
John Wilson, FAS Area Officer
Catherine Otte, FAS
John Prucha, ADA, Program Coordination and Evaluation, OPPDE
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Donald Smart, Director, Review Staff, OFO
Amy Winton, State Department
Nancy Goodwin, ES, IPS, OPPDE
Country File (Italy—Final Audit Report—FY 2001—May 2001)

FSIS:OPPDE:IPS:ES:NGoodwin:mm:720-9187:11/15/01:Italy FY 2001 final audit report to CVO (May 2001)

Clearance:	Initial	Date
Sally Stratmoen, Acting Director, ES, FSIS, IPS	_____	____

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AUDIT REPORT FOR ITALY
MAY 7 THROUGH JUNE 6, 2001

INTRODUCTION

Background

This report reflects information that was obtained during an audit of Italy's meat inspection system from May 7 through June 6, 2001. Twenty-seven of the 141 establishments certified to export meat to the United States were audited. Eight of these were slaughter establishments, and 19 were processing establishments.

The last audit of the Italian meat inspection system was conducted in September 2000. Nine establishments were audited: five establishments were evaluated as acceptable, two establishments were evaluated as acceptable/re-review, and two establishments were evaluated as unacceptable. Hazard Analysis and Critical Control Points (HACCP) systems implementation was deficient in all of the nine establishments visited.

During this new audit, seven of these establishments were included in the itinerary and two were not. Implementation of the required HACCP programs was found to be deficient in six of the seven establishments visited.

The major concerns from the September 2000 audit were the following:

- In all establishments, both establishment and inspection personnel had been unaware of the requirement for a final review of all documentation associated with the production of the product, prior to shipping. The auditor had explained the requirements for this pre-shipment review in detail during the previous audit.

- In the majority of the establishments audited, Government of Italy (GOI) inspection officials were not monitoring/verifying the adequacy and effectiveness of the pre-operational sanitation activities, and records were not maintained or were incomplete.

- In 15 establishments, the HACCP plan did not adequately state the procedures that the establishment would use to verify that the plan was being effectively implemented and the frequencies with which these procedures would be performed. The ongoing verification activities of the HACCP program were not performed adequately, either by either establishment personnel or by GOI meat inspection officials.

- In 12 establishments, the HACCP plan did not adequately specify critical limits for each CCP and the frequency with which these procedures will be performed.

- In 12 establishments, the HACCP plan did not adequately address the corrective actions to be followed in response to deviations from critical limits.

- In 11 establishments, the records for operational sanitation inspection and any corrective actions taken were not being maintained.

- In 11 establishments, monthly supervisory visits were not performed. Only two or three internal reviews were conducted per year by the local or regional officials in these establishments.

- In eight establishments, cross-contamination of product and insanitary handling and storage of product were observed.

- In seven establishments, the zero-tolerance policy for visible fecal material, ingesta, and milk on carcasses had not been enforced by the GOI meat inspection officials and no monitoring records were maintained to verify this activity. None of the slaughter establishments visited had identified the presence of fecal material, ingesta, and milk as food safety hazards and did not address this as a critical control point in their HACCP plans.

- In six establishments, the HACCP plan was not validated to determine that it was functioning as intended.

- In six establishments, the written SSOP did not address operational sanitation.

- In four establishments, product–contact equipment, such as containers of edible product, racks for hams, chutes for edible products, working tables, edible product conveyor belts, band saws, skin removal and bone separation equipment ready for use in the boning and offal rooms and coolers were found with dried fat, grease, blood, and pieces of dried meat.

- In four establishments, the HACCP records did not document the monitoring of critical control points (CCP).

- In three establishments, the written Sanitation Standard Operating Procedure (SSOP) did not address pre-operational sanitation.

- In three establishments, sanitizers were not maintained at the required temperature (82ºC) in the slaughter and boning rooms during operations.

- In one establishment, hog carcasses were not properly identified and controlled to be trimmed effectively.

- The turnaround time for the analysis of *E. coli* and *Salmonella* samples in the government laboratory was four days. Turnaround time should not exceed 24 hours.

Italy exports only processed pork products to the United States. Fresh pork may not be imported due to the presence of hog cholera and swine fever in Italy.

During calendar year 2000, and from January 1 to April 30, 2001, Italian establishments exported 6,482,894 pounds of processed pork products to the United States. Port-of-entry rejections were for contamination (0.37%), miscellaneous defects (0.005 %), and unsound condition (0.01 %).

PROTOCOL

This on-site audit was conducted in four parts. One part involved visits with Italian national meat inspection officials to discuss oversight programs and practices, including enforcement activities. The second part entailed an audit of a selection of records in the meat inspection headquarters and regional facilities preceding the on-site visits. Establishments 14L, 368L, 478L, 627L, 675L, 908L, 1065L, 1170L, 25L, 155L, 350L, 374L, 444L, 613L, 673L, and 744L) were selected randomly for records reviews. The third part involved on-site visits to 27 establishments: 19 processing establishments (972L, 5L, 648L, 240L, 1594L, 515L, 31L, 1157L, 508L, 500L, 363L, 205L, 550L, 172L, 41L, 17L, 272L, 1597L, and 989L) and eight slaughter establishments (92M/S, 272 M/S, 304M/S, 312M/S, 643M/S, 768M/S, 791M/S, and 1664M/S). The processing establishments were selected randomly. However, all eight of Italy's certified slaughterhouses were selected because of concerns arising from the previous on-site audits. The fourth part involved a visit to seven government laboratories that were performing analytical testing of field samples for the national residue testing program and culturing field samples for the presence of microbiological contamination.

Program effectiveness determinations focused on five areas of risk: (1) sanitation controls, including the implementation and operation of Sanitation Standard Operating Procedure (SSOP), (2) animal disease controls, (3) residue controls, (4) slaughter/ processing controls, including the implementation and operation of HACCP programs and the generic *E. coli* testing program, and (5) enforcement controls, including the testing program for *Salmonella* species. Italy's inspection system was assessed by evaluating these five risk areas.

In accordance with the European Union/United States Veterinary Equivalence Agreement, the auditors audited the meat inspection system using European Directives, specifically Council Directives 96/23/EC of April 29, 1996, 96/22/EC of April 29, 1996, and 64/433/EEC of June 1964. These three directives have been declared equivalent under the Agreement. In areas not covered by these directives, the auditors audited against FSIS requirements and equivalence determinations. Only one FSIS equivalence determination had been granted and it concerned the use of a different analytical method for analyzing *Salmonella* samples for the enforcement of *Salmonella* performance standard.

During all on-site establishment visits, the auditors evaluated the nature, extent, and degree to which findings impacted on food safety and public health, as well as overall program delivery. The auditors also determined if establishment and inspection system controls were in place. Establishments that do not have effective controls in place to prevent, detect and eliminate

product contamination/adulteration are considered unacceptable and therefore ineligible to export products to the United States and are delisted accordingly by the country's meat inspection officials. During this current audit, eight establishments were delisted by the GOI because the above controls were not in place.

RESULTS AND DISCUSSION

Summary

Effective inspection system controls were found to be in place in only 19 of the 27 establishments audited: 10 of these 19 (17L, 41L, 172L, 205L, 363L, 500L, 550L, 304M/S, 312M/S, and 791M/S) were recommended for re-review. Eight establishments (92M/S, 272M/S, 643M/S, 768M/S, 1664M/S, 272L, 989L, and 1597L) were found to be unacceptable. Details of the audit findings, including compliance with HACCP, SSOP, and testing programs for *Salmonella* species and generic *E. coli*, are discussed later in this report. Individual establishment reports can be found in Attachment F.

As stated above, numerous major concerns had been identified during the last audit of the Italian meat inspection system, which was conducted in September 2000.

During this new audit, the auditors determined that some of these major concerns had been addressed and corrected by the Italian Ministry of Public Health (MPH). However, the following deficiencies identified in the September 2000 audit had not been addressed and corrected.

- Inadequate implementation and maintenance of HACCP systems.

- Implementation of FSIS' zero-tolerance policy for visible fecal material, ingesta, and milk on carcasses, including failure by the government inspection officials to enforce the policy.

- Inadequate implementation of SSOP. The written SSOP did not address pre-operational or operational sanitation. The records for pre-operational and operational sanitation activities and any corrective actions taken were not being maintained. GOI inspection officials were not monitoring/verifying the adequacy and effectiveness of the pre-operational sanitation activities in the majority of the establishments, and records were not maintained or were incomplete.

- Serious sanitation deficiencies, including direct product contamination, were found in eight of nine establishments visited.

- Inadequate inspection procedures including failure to take corrective actions when sanitation problems were found in the establishments and monthly supervisory visits were not performed in the majority of establishments visited.

Further details are provided in the Sanitation Controls, Slaughter/ Processing Controls, and Enforcement Controls sections of this report.

Entrance Meeting

On May 7, 2001, an entrance meeting was held at the Ministry of Public Health in Rome. The Italian government participants were Dr. Silivo Borrello, Dipartimento Alimenti Nutrizione E Sanita' Pubblica Veterinaria (DANSPV), Director Office VIII; Dr. Franco Fucilli, DANSPV, Veterinary Officer, Office VIII; Dr. Pietro Noe, DANSPV, Veterinary Officer, Office VIII; Dr. Angelo Donato, , DANSPV, Veterinary Officer, Office III; Dr. Agostino Macri, Istituto Superiore di Sanita, Director Veterinary Laboratory; Dr. Marina Paluzzi, and an interpreter.

The United States government participants were Ms. Sally Stratmoen, Chief, Equivalence Section, International Policy Staff, Food Safety and Inspection Service (FSIS); Ms. Geraldine Ransom, Chief, Microbiology Branch, FSIS; Dr. Ghias Mughal, Branch Chief, International Audit Staff, FSIS; Dr. Faizur R. Choudry, International Audit Staff Officer, FSIS; Mr. Clay Hamilton, Agricultural Attaché, United States Embassy, Rome; and Dr. Franco Regini, Agricultural Specialist, United States Embassy, Rome.

Topics of discussion included the following:

- An explanation of the Italian meat inspection system.
- Discussion of the previous audit report and team audit concept.
- The audit itinerary and travel arrangements.

Subsequent to that meeting, the USDA team divided into three subgroups and pursued their individual audit goals. (Team-A on-site audit of inspection system; Team-B on-site audit of inspection system; and Team-C microbiology laboratory audits.)

PART 1—HEADQUARTERS AUDIT

There had been no changes in the organizational structure or upper levels of inspection staffing since the last FSIS audit of Italy's inspection system in September 2000. However, organizational changes to further regionalize inspection were ongoing, since Italy had undergone a decentralization of its inspection operations.

Government Oversight

The Italian meat inspection system is organized in three levels. The first level is the Ministry of Public Health, which includes the Veterinary Service. It is this level of government that FSIS holds responsible for ensuring that FSIS requirements are implemented and enforced. The second level is the regional office level, within which there were 21 regions. These regions were independent from the MPH and there were differences in their organization, staffing and

resources. The third level is the *Aziende Sanitarrie Locali* (ASL), which provides the inspectors for inspection activities.

During this audit, the auditors discovered that since January 1, 2001, the MPH continued to be responsible for certifying establishments to export to the United States but did not have the resources to review individual establishments to determine whether the establishments were operating in accordance with FSIS requirements.

MPH officials advised the auditors that currently its staff consisted of only two inspectors. (During the course of this audit, one of those inspectors resigned.) As such, MPH could not conduct routine supervisory reviews of the U.S. certified establishments to verify the implementation of FSIS requirements.

In eight of the 27 establishments audited on-site, serious inspection problems were found. These problems included failure to recognize and take corrective actions for sanitation problems, failure to verify HACCP implementation, and a lack of understanding of HACCP requirements by either inspection or establishment personnel.

All inspection veterinarians and inspectors in establishments certified by Italy as eligible to export meat products to the United States were full-time Ministry of Public Health Regional/Province/District Government employees, receiving no remuneration from either industry or establishment personnel.

However, the auditors noted that the Italian inspection system was not operating independently. Although the inspectors' salaries were paid by the government, functions normally performed by inspection officials were being performed either by establishment personnel or jointly by inspection and establishment personnel. For example, in one establishment the inspector and establishment personnel were performing the same duties.

Of further concern was the inability of MPH to provide basic resources for the FSIS audit, which resulted in the use of industry personnel to transport auditors to the establishments. Although the issue dealing with functions was resolved early in the audit, the issue of allocation of appropriate resources to support a third party audit still remains.

PART 2—RECORDS REVIEW

The auditors conducted a review of inspection system documents pertaining to the establishments listed for records review. This records review was conducted at the Ministry of Public Health in Rome and at the *Regione Emilia Romagna* in the Bologna offices. The records review focused primarily on food safety hazards and included the following:

- Internal review reports,
- Supervisory visits to establishments that were certified to export to the United States,
- Training records for inspectors and laboratory personnel,
- New laws and implementation documents, such as regulations, notices, directives and guidelines,

- Sampling and laboratory analyses for residues,
- Pathogen reduction and other food safety initiatives such as SSOP, HACCP programs, generic *E. coli* testing, and testing for *Salmonella* species,
- Sanitation, slaughter and processing inspection procedures and standards,
- Control of products from livestock with conditions such as tuberculosis, cysticercosis, etc., and of inedible and condemned materials,
- Export product inspection and control, including export certificates,
- Enforcement records, including examples of criminal prosecutions, consumer complaints, recalls, seizure and control of noncompliant product, and withholding, suspending, or withdrawing inspection services from or delisting an establishment that is certified to export product to the United States.

The following concerns arose as a result the examination of these documents.

HACCP Programs

- The HACCP plans did not adequately specify the critical limits for each CCP and the frequency with which the monitoring procedures would be performed in five establishments.

- The HACCP plans did not adequately address the corrective actions to be taken in response to deviations from critical limits in six establishments.

- The HACCP plans were not validated to determine that they were functioning as intended in six establishments.

- The HACCP plans did not adequately state the procedures that the establishment would use to verify that the plans were being effectively implemented and the frequencies with which these procedures would be performed in seven establishments. Ongoing verification activities of the HACCP programs were not performed adequately either by establishment personnel or by the GOI meat inspection officials.

- There was no documentation of the monitoring of CCPs in one establishment.

Sanitation Standard Operating Procedure (SSOP)

- The written SSOP did not address operational sanitation in two establishments.

- The written SSOPs in one establishment did not address pre-operational sanitation (at a minimum) the cleaning of food-contact surfaces of facilities, equipment, and utensils.

- Daily monitoring records of pre-operational and operational sanitation and any corrective actions taken were not being maintained adequately in 13 establishments.

- GOI meat inspection officials were only monitoring/verifying the adequacy and effectiveness of pre-operational sanitation four to five times a year, and records of these activities were not adequately maintained.

Inspection System Controls

- GOI meat inspection officials were not providing continuous inspection coverage to processing establishments. Inspectors were visiting establishments at variable frequencies such as once per week, two to three times per week, or once per month, and for only an hour or two per visit in 13 establishments.

- Monthly supervisory visits were not performed in eight establishments. Only two or three internal reviews were conducted per year by the regional/provincial or district officials of these establishments.

PART 3—ON-SITE ESTABLISHMENT AUDITS

To gain an accurate overview of the effectiveness of inspection controls, FSIS requested that the audits of the individual establishments be led by the inspection officials who normally conduct the monthly reviews for compliance with United States specifications. The FSIS auditors (hereinafter called "the auditors") observed and evaluated the process.

One hundred forty-one establishments were certified to export meat products to the United States at the time this audit was conducted. Twenty seven establishments (972-L, 5-L, 648-L, 240-L, 1594-L, 515-L, 31-L, 1157-L, 508-L, 500-L, 363-L, 205-L, 550-L, 172-L, 41-L, 17-L, 272-L, 1597-L, 989-L, 92M/S, 272 M/S, 304M/S, 312M/S, 643M/S, 768M/S, 791M/S, and 1664M/S) were visited for on-site audits.

In 19 of these 27 establishments, both Italian inspection system controls and establishment system controls were in place to prevent, detect and control contamination and adulteration of products.

- Nine of the 19 establishments (Ests. 5L, 31L, 240L, 508L, 515L, 648L, 972L, 1157L, and 1594L) were found acceptable.
- Ten of the 19 establishments (Ests.17L, 41L, 172L, 205L, 363L, 500L, 550L, 304M/S, 312M/S, and 791M/S) were rated acceptable re-review because of deficiencies regarding sanitation, condition of facilities, and noncompliance with HACCP requirements.

Eight establishments (92M/S, 272M/S, 643M/S, 768M/S, 1664M/S, 272L, 989L, and 1597L) were found to be unacceptable because of critical sanitation problems and findings of direct product contamination.

Establishment Operations by Establishment Number

The following operations were being conducted in the 27 establishments:

Pork slaughter and boning—eight establishments (92M/S, 272M/S, 304M/S, 312M/S, 643M/S, 768M/S, 791M/S, and 1664M/S)

Pork boning and prosciutto/cooked ham--18 establishments (972L, 5L, 648L, 240L, 1594L, 515L, 1157L, 508L, 31L, 500L, 363L, 205L, 550L, 172L, 41L, 17L, 272L, 1597-L, 17L, and 989L)

SANITATION CONTROLS

As stated earlier, the auditor focuses on five areas of risk when assessing a foreign country's inspection system. The first of these risk areas that the auditor looks at is Sanitation Controls. These controls include the implementation and operation of SSOP programs in certified establishments, all aspects of facility and equipment sanitation, actual or potential instances of product cross-contamination, personal hygiene and practices, and product handling and storage.

Based on the on-site audits of establishments, Italy's inspection system had controls in place for water potability records; chlorination procedures; back-siphonage prevention; separation of operations; temperature control; work space; ventilation; ante-mortem facilities; welfare facilities; outside premises; personal dress and habits; and pest control monitoring.

The auditors' findings are presented below for the areas of SSOP, cross-contamination, product handling and storage, and personal hygiene and practices.

Sanitation Standard Operating Procedure (SSOP)

Each establishment was evaluated to determine if the basic FSIS regulatory requirements for SSOP were met, according to the criteria employed in the U.S. domestic inspection program. The data collection instrument used accompanies this report (Attachment A).

The SSOP in the 27 establishments were found to meet the basic FSIS regulatory requirements, with the following deficiencies.

- In two establishments, the written SSOP procedure did not address pre-operational sanitation.
- In nine establishments, the written SSOP did not address operational sanitation.
- In one establishment, the written SSOP procedure did not indicate frequency of the tasks.
- In one establishment, the SSOP procedure did not identify the individual responsible for implementing and maintaining the activities.
- In nine establishments, the records for SSOP operational sanitation and any corrective action taken were not being maintained.
- In one establishment, the written SSOP procedure was not dated and signed by the person with overall on-site authority.

Cross-Contamination: In the area of cross-contamination, actual product contamination and the potential for product contamination was found in 19 out of 27 establishments audited. In some

establishments, but not all, the GOI took corrective actions. Specific findings for each establishment audited on-site can be found in Attachment F.

Examples of findings of actual product contamination include:

- In 13 establishments, dripping condensate, from overhead refrigeration units, ceilings, pipes, rail, ducts, and air vents that were not cleaned/sanitized daily, was falling onto carcasses and exposed edible product in the coolers, boning, offal, packaging room, corridors, spice room, ham pumping room, cooked product holding room, ham tumbler room, and slaughter rooms.

- In 12 establishments, sanitizers were not maintained at the required temperature (82ºC) in the slaughter and boning rooms during operation. In three of these establishments, the sanitizing facility for knives in the slaughter and boning rooms was designed in such a way that it was not possible to sanitize knives completely and effectively. In two of these establishments, the facility for carcass circular saw to wash/sanitize was not provided when required in the boning room and the other establishment, there was no procedure to identify that the knives had been kept in the UV sterilizer for 30 minutes as described in the instructions.

- In 20 establishments, insanitary equipment was directly contacting edible product in the boning rooms, coolers, slaughter rooms, defrosting rooms, spice room, processing rooms, and brine pumping rooms. For example, containers of edible product, racks for ham, plastic cutting boards, working tables, automatic viscera conveyor, hopper for edible product, meat hooks, and chutes for edible product were found with fat, dried pieces of meat, blood, grease, dirt, black discoloration. In some establishments, equipment used for edible product was found with open seams, deeply scored cutting boards, metal and plastic containers sealed with silicone caulking. In other establishments, conveyor belt for edible product was cracked and deteriorated in processing rooms.

- In four establishments, water was leaking from an overhead pipes and water splash from the viscera conveyor washing cabinet, ham pumping room, ceilings, and air vents onto edible offal and carcasses in the slaughter room.

- In five establishments, the automatic offal and hog heads hook conveyor in the slaughter room was soiled with blood, fat, and ingesta after washing/sanitizing in the slaughter room and in two establishments, water was falling onto hog carcasses from carcass splitting saw at the carcass splitting station. In one establishment, hog carcasses were contacting dirty hose during carcass splitting in the slaughter room. In one establishment, numerous plastic coverings were broken and exposed edible product was contacting dirty pallets in the freezer.

Examples of findings of potential cross-contamination of product include:

- In 12 establishments, overhead refrigeration units and ceilings, pipes, beams, supports, rails, fans, vent screens, frame of light fixtures, and air socks in the coolers, boning room, ham tumbling room, cooking room, slaughter room, offal room, retained carcass cooler, and

processing room were observed with accumulations of fat, old meat scraps, and black stains, rust, flaking paint, dirt, dust, grease, and cobwebs.

- In one establishment, the automatic conveyor belt for edible product during return in the hot boning room was contacting employees' boots and there was also the potential for cross-contamination from splash water from the wet floor.

- In another establishment, several doors in the boning and processing rooms opened upwards and wet floors below the doors resulted in the potential for cross-contamination from dripping dirty water on employees' clothes and exposed edible product when passing through the doors.

- In a third establishment, water was overflowing on the floor due to clogged drain from handwashing lavatory in the carcass sticking area.

Personal Hygiene and Practices: In the area of personal hygiene and practices, the following deficiencies were noted.

- In two establishments, exposed edible-product was contacting walls and dirty plastic wires during transportation.

- In two establishments, light was inadequate at the hog head inspection stations in the slaughter room.

- In four establishments several employees' were observed picking up dirty gloves, dropped carcass and dirty pallets from the floor, cleaning floor with a broom, handling inedible product, using a dirty steel which was kept in the sink, and without washing their hands and washing/sanitizing dirty equipment, handling edible product and a few employees' were using steel meshed and cotton gloves prior to post-mortem inspection which were not covered with plastic gloves to prevent cross contamination.

- In four establishments, walls, floors, and several electrical switches in the coolers, cooked ham room, meat grinding/mixing room were found with dried pieces of meat, fat, dirt, flaking paint, and floors were not properly drained to prevent puddling.

- In seven establishments, the packaging material was not kept separate from unused equipment or other junk and a build up of dust or debris, cobwebs was observed in the dry storage rooms. In another establishment, rodenticides were spilled on the floor from a few bait boxes in dry storage room.

- In 12 establishments, overhead refrigeration units and ceilings, pipes, beams, supports, rails, fans, vent screens, frame of light fixtures, and air socks in the coolers, boning room, ham tumbling room, cooking room, slaughter room, offal room, retained carcass cooler, and processing room were observed with accumulations of fat, old meat scraps, and black stains, rust, flaking paint, dirt, dust, grease, and cobwebs.

Product Handling and Storage: In the area of product handling and storage, the following deficiencies were noted.

- In five establishments, edible product that contacted the floor (dropped meat) was not reconditioned in a sanitary manner before being added to the edible product.

- In seven establishments, containers for edible and inedible product were not identified or stored separately to prevent possible cross-contamination.

- In nine establishments pest control prevention was inadequate. For example, in one establishment gaps at the bottoms of doors in the product receiving and workshop rooms and in three establishments in the processing rooms were not sealed properly to prevent the entry of rodents and other vermin. In two establishments, the emergency door in the slaughter room and door leading to outside in the scalding room were left open. In three other establishments, gaps at the bottoms of doors in dry storage rooms were not sealed properly to prevent the entry of rodents and other vermin.

ANIMAL DISEASE CONTROLS

The second of the five risk areas that the auditor looks at is Animal Disease Controls. These controls include ensuring adequate animal identification, control over condemned and restricted product, and procedures for sanitary handling of returned and rework product. Except as noted below, Italy's inspection system had adequate controls in place to ensure control over the above areas.

- In seven establishments, inedible product was not denatured/decharacterized or placed under security before shipping for rendering. GOI inspection officials did not take any corrective action.

There were reported to have been no outbreaks of animal diseases with public-health significance since the previous U.S. audit. MPH inspection officials indicated that approximately 100,000 bovine were tested for Bovine Sponigiform Encephalopathy and 14 were found positive. The U.S. does not import any beef from Italy. In addition, Italy is not free from hog cholera and swine vesicular disease. Although Italy is currently free of Food and Mouth Disease, special restrictions apply to meat products because Italy shares a border with a country or countries that is not free of Foot and Mouth Disease.

RESIDUE CONTROLS

The third of the five risk areas that the auditor looks at is Residue Controls. These controls include sample handling and frequency, timely analysis, data reporting, tissue matrices for analysis, equipment operation and printouts, minimum detection levels, recovery frequency, percent recoveries, and corrective actions.

The Instituti Zooproficlattici Sperimentali- Laboratory in Torino was audited on May 17, 2001.

The following deficiency was noted.

- Percent recovery for polychlorinated biphenyls (PCBs) was below the acceptable range (51.3%), and no corrective actions were taken. The acceptable range is 70 to 110%.

The auditors found that Italy's National Residue Testing Plan for 2001 was being followed and was on schedule. The GOI had adequate controls in place to ensure compliance with sampling and reporting procedures and storage and use of chemicals. The methods used for the analyses were acceptable.

SLAUGHTER/PROCESSING CONTROLS

The fourth of the five risk areas that the auditor looks at is Slaughter/Processing Controls. The controls include the following areas: adequate animal identification; ante-mortem inspection procedures; ante-mortem disposition; humane slaughter; post-mortem inspection procedures; post-mortem dispositions; ingredients identification; control of restricted ingredients; formulations; processing schedules; equipment and records; and processing controls of cured, dried, and cooked products. The controls also include the implementation of HACCP systems in all establishments and a generic *E. coli* testing program in slaughter establishments. Deficiencies are discussed below.

HACCP Implementation: All establishments approved to export meat products to the U.S. are required to have developed and implemented a HACCP system. Each of these systems was evaluated according to the criteria employed in the U.S domestic inspection program. The data collection instrument used accompanies this report (Attachment B).

The HACCP programs were reviewed during the on-site audits of 27 establishments. The auditors found the following deviations from FSIS' regulatory requirements.

- In one establishment, there was no written HACCP plan for each product where the hazard analysis revealed one or more food safety hazard(s) reasonably likely to occur.

- In two establishments, the HACCP plan did not have a flow chart that describes the process steps and product flow.

- In three establishments, the HACCP plan did not address the intended use of or the consumers of the finished product(s).

- In four establishments, the HACCP plan was not dated and signed by a responsible establishment official.

- In five establishments, the HACCP plan did not conduct a hazard analysis.

- In seven establishments, the HACCP plan's record keeping system was not documenting the monitoring of CCPs.

- In 13 establishments, the HACCP plan was not validated to determine if it was functioning as intended.

- In 15 establishments, the HACCP plan did not specify critical limits for each CCP and the frequency with which these procedures would be performed.

- In 17 establishments, the HACCP plan did not address adequately the corrective actions to be followed in response to deviations from critical limits.

- In 17 establishments, the HACCP plan did not state adequately the procedures that the establishment would use to verify that the plan was being effectively implemented and the frequencies with which these procedures would be performed. The ongoing verification activities of the HACCP program were not performed adequately either by the establishment personnel or by the GOI meat inspection officials.

Testing for Generic *E. coli*

Italy has adopted the FSIS regulatory requirements for generic *E. coli* testing. Eight of the 27 establishments audited were required to meet the basic FSIS regulatory requirements for generic *E. coli* testing. These eight establishments were evaluated according to the criteria employed in the U.S. domestic inspection program. The data collection instrument used accompanies this report (Attachment C).

The following deficiencies were noted.

- In one establishment, the procedure did not designate the employee(s) responsible to collect the samples.

- In two establishments, the sampling was not done at the frequency specified in the procedure.

- In two establishments, the carcass selection was not made randomly and random method was not specified in the procedure.

- In three establishments, the sequence of carcass sponging was not being followed properly such as belly, ham, and jowl instead of ham, belly, and jowl.

- In three establishments, the test results were not being recorded on a process control chart showing the most recent test results.

ENFORCEMENT CONTROLS

The fifth of the five risk areas is Enforcement Controls. These controls include the enforcement of inspection requirements and the testing program for *Salmonella* species.

Except as noted below, the GOI had controls in place for ante-mortem and post-mortem inspection procedures and dispositions, restricted product and inspection samples, disposition of

dead, dying, diseased or disabled animals, shipment security, including shipment between establishments, and prevention of commingling of product intended for export to the U.S. with domestic product.

In addition, controls were in place for inspection supervision and documentation, the importation of only eligible livestock or poultry from other countries, i.e., only from eligible third countries and certified establishments within those countries, and the importation of only eligible meat or poultry products from other counties for further processing. Adequate controls were found to be in place for security items, shipment security, and products entering the establishments from outside sources.

Testing for *Salmonella* Species

Prior to this audit Italy had advised FSIS that it had adopted all of the FSIS requirements for *Salmonella* species testing with the sole exception of the use of different analytic methods. FSIS had determined that Italy's use of the ISO 6579 and AOAC 967.25 methods were equivalent to FSIS' requirements.

Eight of the establishments audited were required to meet the basic FSIS regulatory requirements for *Salmonella* testing, and were evaluated according to the criteria employed in the U.S. domestic inspection program. The data collection instrument used accompanies this report (Attachment D).

The following general deficiencies were noted.

- Throughout and within regions, *Salmonella* samples were collected and analyzed in one of three ways: (1) establishment personnel were selecting the samples and using private laboratories for analysis, (2) government employees were collecting the samples and using private laboratories for analysis, and (3) government employees were collecting the samples and using government laboratories for testing. The only scenario currently approved by FSIS is the use of government employees and government laboratories.

- Microbiology methods in-use tended to be based on standard methods. However, some laboratories use modified standard methods, and are not strictly adhering to standard protocols. Modifications to standard methods are not acceptable.

The following specific deficiencies were noted.

- In four establishments, the samples were not being taken randomly.

- In four establishments, the sequence of carcass sponging was not being followed properly such as belly, ham, and jowl instead of ham, belly, and jowl.

Species Verification Testing

At the time of this audit, Italy was not exempt from the species verification-testing requirement. The auditors verified that species verification testing was being conducted in accordance with FSIS requirements.

Listeria monocytogenes Testing

Establishments producing ready-to-eat products are required to reassess their HACCP plans to determine if *Listeria monocytogenes* should be considered as a hazard reasonably likely to occur. These establishments must also implement a *Listeria monocytogenes* testing program for ready-to-eat products.

The following deficiency was noted.

- The control of *Listeria monocytogenes* in not included in the HACCP plans in those establishments producing ready-to-eat products.

Monthly Reviews

The internal review program was applied equally to both export and non-export establishments. Internal review visits were both announced and not announced in advance, and were conducted, at times by individuals and at other times by a team of reviewers, in most establishments only two or three reviews per year. The records of audited establishments were kept in the inspection offices of the individual establishments, and copies were also kept in the regional/provincial/district offices.

These reviews were being performed by the regional/provincial/district officials equal to FSIS district managers or circuit supervisors. These officials were all veterinarians.

In the event that an establishment is found, during one of these internal reviews, to be out of compliance with U.S. requirements, and is delisted for U.S. export, before it may again be eligible be reinstated, regional/provincial/district officials conduct an in-depth review, and the results are reported to Dr. Piergiuseppe Facelli, Direttore Ufficio III, Ministerio della Sanita, Dipartimento Alimenti Nutrizione e Sanita Pubblica Veterinaria, in Rome for evaluation. A plan is formulated for corrective actions and preventive measures.

The following deficiencies were noted.

- In 14 establishments, GOI meat inspection officials were not providing continuous inspection coverage to processed products establishments. Inspectors were visiting establishments at variable frequencies such as once a week, two to three times a week, or once a month and between one to two hours each visit.

- In 16 establishments, monthly supervisory visits were not performed. Only two or three internal reviews were conducted per year by the regional/provincial/district officials or establishment veterinarians.

Other Enforcement Activities

Controls were in place to ensure adequate export product identification, inspector verification, export certificates, a single standard of control throughout the establishments, and adequate controls for security items, shipment security, and products entering the establishments from outside sources.

Enforcement activities are carried out by regional/provincial/district government officials, which have full power to initiate all enforcement actions.

The following deficiencies were noted.

Inspection System Controls

- In one establishment, the mandibular lymph nodes of hog heads were not incised during post-mortem inspection.

- In one establishment, hog carcass was presented with missing offal (liver, lungs, heat, and tongue) for final post-mortem inspection. The veterinarian passed the carcass without inspection of offal and retained hog carcasses for final post-mortem disposition were not identified by the GOI inspection service in the cooler (Noncompliance with Council Directive 64/433/EEC of 26 June 1964. Chapter VI-25.)

- In one establishment, hogs were not stunned in such a manner that they would be rendered unconscious with a minimum excitement and discomfort such as one hog was observed staggering and crawling on the top of other stunned hogs and its throat was slit by the employee without any further stunning.

- In six establishments, the final review of all documentation associated with the production of the product prior to shipping was not done.

- In six establishments, the zero-tolerance for visible fecal material/ingesta contamination, and milk on carcasses were not enforced by the GOI meat inspection officials, and there was no monitoring record maintained to verify this activity.

- In seven establishments, inedible product was not denatured/decharacterized or under security before shipping for rendering.

- In 23 establishments, periodic supervisory visits were not performed monthly. Only two or three internal reviews were conducted per year by the regional/provincial/ district officials or establishment veterinarians.

- In 27 establishments, GOI meat inspection officials were not providing continuous inspection coverage. Inspectors were visiting establishments at variable frequencies such as two to three times a week, once a week, or once a month and between one to two hours each visit.

PART 4—LABORATORY AUDITS

During the laboratory audits, emphasis was placed on the application of procedures and standards that were equivalent to U.S. requirements. Information about the following risk areas was also collected:

1. Government oversight of accredited, approved, and private laboratories.
2. Intra-laboratory quality assurance procedures, including sample handling.
3. Methodology.

Residue Laboratory Audit

The Instituti Zooproficlattici Sperimentali- Laboratory in Torino was audited on May 17, 2001. Effective controls were in place for sample handling and frequency, timely analysis, data reporting, tissue matrices for analysis, equipment operation and printouts, minimum detection levels, recovery frequency, percent recoveries, and corrective actions. The methods used for the analyses were acceptable.

The following deficiency was noted.

- Percent of recovery for polychlorinated biphenyls (PCBs) was below the acceptable range (51.3%). The acceptable range is 70 to 110%.

Microbiology Laboratory Audits

Seven Italian government laboratories were audited. Emphasis was placed on the application of procedures and standards that were equivalent to United States requirements.

Six Instituti Zooprofilattici were reviewed, including a central Rome headquarters site that houses the government national reference laboratory for *Salmonella*. The majority of Instituti Zooprofilattici visited are central regional Instituti Zooprofilattici laboratories that set policy for and oversee numerous laboratories that operate in the same regions. The Ancona and Firenze Instituti Zooprofilattici sites are not central laboratories. The seventh laboratory visited was the Rome Instituto Superior Della Sanita (ISS) Food Microbiology Section. This institute is not an Instituto Zooprofilattico, but serves as an authority to Instituti Zooprofilattici.

- Generally, the laboratories were orderly, well equipped, of ample size, and efficiently run. Personnel were knowledgeable, well trained, and appeared competent.

- Most laboratories were not aware if they were testing product for U.S. export, or stated that they were not. Carcass sponge samples for *Salmonella* or generic *E. coli* are not routinely tested at these laboratories.

- The taking and testing of *Salmonella* samples varied widely throughout the regions. In some establishments, establishments were taking samples and the samples were being analyzed in private laboratories. In other establishments, the government was taking the samples and the samples were being analyzed in private laboratories. In other establishments, the government was taking the samples and the samples were being analyzed in government laboratories. In documents submitted by Italy and evaluated by FSIS, Italy stated that all *Salmonella* samples would be taken by government employees and analyzed in government laboratories. The auditors found that this was not the case.

- Microbiology methods in-use tended to be based on standard methods. However, some laboratories use modified standard methods, and were not strictly adhering to standard protocols.

- Laboratories were analyzing only a 25-gram *Salmonella* sample of ready-to-eat product, in contrast to 325-gram sample size required in the U.S.

Instituti Zooprofilattici laboratories are accredited externally through SINAL, covering the entire system as well as individual testing protocols. SINAL audits are annual. The laboratories are also subject to twice yearly internal quality assurance audits and internal quality assurance programs are in place.

Exit Meetings—Rome, Italy and Brussels, Belgium

Two exit meetings were conducted. One was conducted at the Ministry of Public Health in Rome, on June 4, 2001. The participants from Italy were Dr. Romano Marabelli, General Director, Department of Food Nutrizion and Public Veterinary Health; Dr. Piergiuseppe Facelli, Direttore Ufficio III, (DANSPV); Dr. Silivo Borrello, Dipartimento Alimenti Nutrizione E Sanita' Pubblica Veterinaria (DANSPV), Director Office VIII; Dr. Pietro Noe, DANSPV, Veterinary Officer, Office VIII; Dr. Angelo Donato, , DANSPV, Veterinary Officer, Office III; Dr. Marina Paluzzi, DANSPV, Interpreter; Dr. Castoldi, Regional Veterinary Service (RVS) Lombardia; Dr. Galesso, RVS Veneto; DR. Sigismondi, RVS Lazio; Dr. Principi, RVS Lazio; Dr. Gioranoni, RVS Lazio; Dr. Picrantoni, RVS Emilia Romagna; and Dr. Alberto Mancuso, RVS Piemonte.

The participants from the United States were Ms. Sally Stratmoen, Chief, Equivalence, International Policy Staff, FSIS; Dr. Ghias Mughal, Branch Chief, International Review Staff, FSIS; Dr. Faizur R. Choudry, International Audit Staff Officer, FSIS; Mr. Clay Hamilton, Agricultural Attaché, Foreign Agricultural Service, United States Embassy; and Dr. Franco Regini, Agricultural Specialist, Foreign Agricultural Service, United States Embassy, Rome.

A second exit meeting was conducted with the European Commission (EC) in Brussels, Belgium on May 6, 2001. The participants from the EC were Dr. Jens Nymand-Christensen, Head of Unit, Health and Consumer Protection Directorate General (SANCO); Dr. Paolo M. Drostby, DG, SANCO, Unit E-3; Dr. T. E. Golden, DG, SANCO, Unit D-2; and Dr. Marco Castellina, Consigliere per le Questioni Sanitarie, Rappresentanza Permanente D'Italia.

The participants from the United States were Ms. Sally Stratmoen, Chief, Equivalence, International Policy Staff, FSIS; Dr. Ghias Mughal, Branch Chief, International Review Staff, FSIS; Dr. Faizur R. Choudry, International Audit Staff Officer, FSIS; Ms. Melinda D. Sallyards, Agricultural Attaché, United States Mission to the European Union, Foreign Agricultural Service, Brussels.

The following topics were discussed:

1. The continuing problems with the implementation and maintenance of SSOP in certified establishments.
2. The continuing problems with implementation and maintenance of HACCP systems in certified establishments.
3. Instances of actual product contamination and instances of the potential for direct product contamination.
4. Inadequate inspection system controls, including the denaturing of condemned or inedible products, enforcement of humane slaughter laws, use of inspection procedures to check for disease, and carcass and offal inspection requirements.
5. The lack of continuous inspection coverage in establishments producing products for export to the U.S.
6. Deficiencies in the *Salmonella* sampling and testing program.
7. The lack of periodic supervisory reviews of certified establishments.
8. Deficiencies in Italy's microbiological laboratory testing programs.

Dr. Romano Marabelli, General Director, Department of Food Nutrition and Public Veterinary Health stated that he would take the necessary steps to ensure that corrective actions and preventive measures, including HACCP, SSOP, sanitation problems, and monthly visits as promised during the audits and exit meetings in the individual establishments would be implemented.

CONCLUSION

The Italian meat inspection system has major deficiencies, which demonstrate a lack of government oversight as evidenced by the findings presented in the report.

Twenty-seven establishments were audited: nine were acceptable, ten were evaluated as acceptable/re-review, and eight were unacceptable. The GOI meat inspection officials reinforced the assurances made by the field personnel during and at the conclusions of the on-site audits of the establishments, and stated that they would ensure prompt compliance. However, these assurances have been given previously at the conclusion of the February 1998, January 1999, and September 2000 audits, yet little if any corrective actions have been taken.

Several serious deficiencies were found in Italy's *Salmonella* testing programs, specifically the use of establishment personnel to select samples and testing of the samples in private laboratories, the modification of approved testing methods for *Salmonella,* and an inadequate sample size for testing ready-to-eat products for *Salmonella*.

Dr. Faizur R. Choudry
International Audit Staff Officer

(signed)Dr. Faizur R. Choudry

ATTACHMENTS

A. Data collection instrument for SSOP
B Data collection instrument for HACCP programs
C. Data collection instrument for *E. coli* testing.
D. Data collection instrument for *Salmonella* testing
E. Laboratory audit forms
F. Individual Foreign Establishment Audit Forms
G. Written Foreign Country's Response to the Draft Final Audit Report

Attachment A

Data Collection Instrument for SSOP

Each establishment was evaluated to determine if the basic FSIS regulatory requirements for SSOP were met, according to the criteria employed in the U.S. domestic inspection program. The data collection instrument contained the following statements:

1. The establishment has a written SSOP program.
2. The procedure addresses pre-operational sanitation.
3. The procedure addresses operational sanitation.
4. The pre-operational procedures address (at a minimum) the cleaning of food-contact surfaces of facilities, equipment, and utensils.
5. The procedure indicates the frequency of the tasks.
6. The procedure identifies the individuals responsible for implementing and maintaining the activities.
7. The records of these procedures and any corrective action taken are being maintained on a daily basis.
8. The procedure is dated and signed by the person with overall on-site authority.

The results of these evaluations were as follows:

Est. #	1.Written program addressed	2. Pre-op sanitation addressed	3. Oper. sanitation addressed	4. Contact surfaces addressed	5. Fre-quency addressed	6. Responsi ble indiv. identified	7. Docume-ntation done daily	8. Dated and signed
92 M/S	√	√	NO	√	√	√	√	√
272 M/S	√	√	NO	√	√	√	NO	√
312 M/S	√	√	NO	√	√	√	NO	√
304 M/S	√	√	√	√	√	√	NO	√
643 M/S	√	NO	√	√	√	√	NO	√
768 M/S	√	NO	NO	√	√	√	√	√
791M/S	√	√	√	√	√	√	√	√
272L	√	√	NO	√	√	√	NO	√
989-L	√	√	NO	√	√	√	NO	√
363-L	√	√	NO	√	√	√	√	√
240L	√	√	√	√	√	√	√	√
550L	√	√	√	√	√	√	√	√
515L	√	√	√	√	√	√	√	√
31L	√	√	√	√	√	√	√	√
1597L	√	√	NO	√	NO	NO	NO	NO
972L	√	√	√	√	√	√	√	√
500L	√	√	√	√	√	√	√	√
205L	√	√	√	√	√	√	√	√
5L	√	√	√	√	√	√	√	√
648L	√	√	√	√	√	√	√	√

Est. #	1.Written program addressed	2. Pre-op sanitation addressed	3. Oper. sanitation addressed	4. Contact surfaces addressed	5. Frequency addressed	6. Responsible indiv. identified	7. Documentation done daily	8. Dated and signed
1664M/S	√	√	√	√	√	√	√	√
1594L	√	√	√	√	√	√	√	√
508L	√	√	√	√	√	√	√	√
172L	√	√	√	√	√	√	√	√
1157L	√	√	NO	√	NO	NO	NO	NO
41L	√	√	√	√	√	√	√	√
17L	√	√	√	√	√	√	NO	√

Documentation was also audited from the following establishments that were not visited on-site.

Est. #	1.Written program addressed	2. Pre-op sanitation addressed	3. Oper. sanitation addressed	4. Contact surfaces addressed	5. Frequency addressed	6. Responsible indiv. identified	7. Documentation done daily	8. Dated and signed
14-L	√	√	√	√	√	√	NO	√
25-L	√	√	√	√	√	√	√	√
350-L	√	√	√	√	√	√	√	√
368-L	√	√	NO	√	√	√	NO	√
613-L	√	√	√	√	√	√	√	√
908-L	√	√	√	√	√	√	√	√
374-L	√	√	√	√	√	√	NO	√
1170-L	√	√	√	√	√	√	√	√
478-L	√	√	√	√	√	√	√	√
675-L	√	√	√	√	√	√	NO	√
1065-L	√	√	√	√	√	√	√	√
155-L	√	√	√	√	√	√	√	√
744-L	√	√	√	√	√	√	√	√
444-L	√	√	√	√	√	√	√	√
673-L	√	√	NO	NO	√	√	√	√

Attachment B

Data Collection Instrument for HACCP Programs

Each of the establishments approved to export meat products to the U.S. was required to have developed and implemented a Hazard Analysis and Critical Control Point (HACCP) system. Each of these systems was evaluated according to the criteria employed in the U.S. domestic inspection program. The data collection instrument included the following statements:

1. The establishment has a flow chart that describes the process steps and product flow.
2. The establishment has conducted a hazard analysis that includes food safety hazards likely to occur.
3. The analysis includes the intended use of or the consumers of the finished product(s).
4. There is a written HACCP plan for each product where the hazard analysis revealed one or more food safety hazard(s) reasonably likely to occur.
5. All hazards identified in the analysis are included in the HACCP plan; the plan lists a CCP for each food safety hazard identified.
6. The HACCP plan specifies critical limits, monitoring procedures, and the monitoring frequency performed for each CCP.
7. The plan describes corrective actions taken when a critical limit is exceeded.
8. The HACCP plan was validated using multiple monitoring results.
9. The HACCP plan lists the establishment's procedures to verify that the plan is being effectively implemented and functioning and the frequency for these procedures.
10. The HACCP plan's record-keeping system documents the monitoring of CCPs and/or includes records with actual values and observations.
11. The HACCP plan is dated and signed by a responsible establishment official.
12. The establishment is performing routine pre-shipment document reviews.

The results of these evaluations were as follows:

Est. #	1. Flow diagram	2. Hazard analysis conduct-ed	3. Use & users includ-ed	4. Plan for each hazard	5. CCPs for all hazards	6. Monitoring is spec-ified	7. Corr. actions are des-cribed	8. Plan valida-ted	9. Ade-quate verific. proced-ures	10.Ade-quate docu-menta-tion	11. Dat-ed and signed	12.Pre-shipmt. doc. review
92 M/S	√	NO	√	√	√	NO	NO	NO	NO	NO	√	√
272 M/S	√	√	√	√	√	NO	NO	NO	NO	NO	NO	NO
312 M/S	√	√	√	√	√	NO	NO	√	NO	NO	√	NO
304 M/S	√	NO	√	√	√	NO	NO	NO	NO	√	√	√
643 M/S	√	√	√	√	√	NO	NO	NO	NO	NO	√	√
768 M/S	√	√	√	√	√	NO	NO	NO	NO	√	√	√
791M/S	√	NO	√	√	√	NO	NO	NO	NO	√	√	√
272-L	√	√	√	√	√	NO	NO	NO	NO	√	NO	NO
989-L	√	√	NO	√	√	NO	NO	NO	NO	NO	√	NO
363-L	NO	√	√	NO	√	√	√	√	NO	√	√	√
240-L	√	√	√	√	√	√	NO	√	√	√	√	√
550-L	√	NO	√	√	√	NO	NO	√	NO	√	√	√
515-L	√	√	√	√	√	NO	NO	NO	NO	√	√	√
31-L	√	√	√	√	√	NO	NO	√	NO	√	√	√
17-L	√	√	√	√	√	√	NO	√	√	√	√	√
1597-L	NO	NO	√	√	NO	√	NO	NO	NO	NO	NO	NO
972-L	√	√	√	√	√	√	NO	√	√	√	√	√

500L	√	√	√	√	√	√	NO	√	√	√	√	√
205L	√	√	√	NO	√	√	√	NO	NO	√	√	√
5L	√	√	√	√	√	√	NO	√	√	NO	√	√
648L	√	√	√	√	√	√	√	√	√	√	√	√
1664M/S	√	√	√	√	√	NO	NO	NO	NO	√	NO	NO
1594L	√	√	√	√	√	√	√	√	√	√	√	√
172L	√	√	√	√	√	√	√	√	√	√	√	√
1157L	√	√	√	√	√	√	√	√	√	√	√	√
508L	√	√	√	√	√	√	√	√	√	√	√	√
41L	√	√	√	√	√	√	NO	NO	√	√	√	√

Documentation was also audited from the following establishments that were not visited on-site.

Est. #	1. Flow diagram	2. Hazard analysis conducted	3. Use & users included	4. Plan for each hazard	5. CCPs for all hazards	6. Monitoring is specified	7. Corr. actions are described	8. Plan validated	9. Adequate verific. procedures	10.Adequate documentation	11. Dated and signed	12.Pre-shipmt. doc. review
14-L	√	√	√	√	√	√	√	√	√	√	√	√
25-L	√	√	√	√	√	NO	NO	NO	NO	√	√	√
350-L	√	√	√	√	√	NO	NO	NO	NO	√	√	√
368-L	√	√	√	√	√	NO	NO	NO	NO	√	√	√
613-L	√	√	√	√	√	NO	NO	NO	NO	√	√	√
908-L	√	√	√	√	√	√	NO	√	NO	√	√	√
1170-L	√	√	√	√	√	√	√	√	√	√	√	√
478-L	√	√	√	√	√	√	√	√	√	NO	√	√
675-L	√	√	√	√	√	√	√	√	√	√	√	√
1065-L	√	√	√	√	√	√	√	√	√	√	√	√
155-L	√	√	√	√	√	√	√	√	√	√	√	√
744-L	√	√	√	√	√	√	√	√	√	√	√	√
444-L	√	√	√	√	√	√	√	√	√	√	√	√
673-L	√	√	√	√	√	√	√	√	√	√	√	√
374-L	√	√	√	√	√	NO	NO	NO	NO	√	√	√

NOTE: Establishment 627-L was randomly selected for record audit but it was removed from U.S. approved list by the MPH inspection service effective May 9, 2001, as requested by the establishment.

Attachment C

Data Collection Instrument for Generic *E. coli* Testing

Each establishment was evaluated to determine if the basic FSIS regulatory requirements for generic *E. coli* testing were met, according to the criteria employed in the U.S. domestic inspection program. The data collection instrument contained the following statements:

1. The establishment has a written procedure for testing for generic *E. coli.*
2. The procedure designates the employee(s) responsible to collect the samples.
3. The procedure designates the establishment location for sample collecting.
4. The sample collection is done on the predominant species being slaughtered.
5. The sampling is done at the frequency specified in the procedure.
6. The proper carcass site(s) and/or collection methodology (sponge or excision) is being used for sampling.
7. The carcass selection is following the random method specified in the procedure or is being taken randomly.
8. The laboratory is analyzing the sample using an AOAC Official Method or an equivalent method.
9. The results of the tests are being recorded on a process control chart showing the most recent test results.
10. The test results are being maintained for at least 12 months.

Est. #	1.Written procedure	2. Sampler designated	3.Sampling location given	4. Predomin. species sampled	5. Sampling at the req'd freq.	6. Proper site or method	7. Sampling random	8. Using AOAC method	9. Chart or graph of results	10. Results are kept at least 1 yr
92 M/S	√	√	√	√	√	√	√	√	NO	√
272 M/S	√	√	√	√	NO	NO	√	√	NO	√
312 M/S	√	√	√	√	√	√	NO	√	√	√
304 M/S	√	NO	√	√	√	NO	√	√	√	√
643 M/S	√	√	√	√	√	√	√	√	√	√
768 M/S	√	√	√	√	√	NO	√	√	NO	√
791M/S	√	√	√	√	√	√	√	√	√	√
1664M/S	√	√	√	√	NO	NO	NO	√	√	√

Attachment D

Data Collection Instrument for *Salmonella* Testing

Each slaughter establishment was evaluated to determine if the basic FSIS regulatory requirements for *Salmonella* testing were met, according to the criteria employed in the U.S. domestic inspection program. The data collection instrument included the following statements:

1. *Salmonella* testing is being done in this establishment.

2. Carcasses are being sampled.

3. Ground product is being sampled.

4. The samples are being taken randomly.

5. The proper carcass site(s) and/or collection of proper product (carcass or ground) is being used for sampling.

6. Establishments in violation are not being allowed to continue operations.

The results of these evaluations were as follows:

Est. #	1. Testing as required	2. Carcasses are sampled	3. Ground product is sampled	4. Samples are taken randomly	5. Proper site and/or proper prod.	6. Violative est's stop operations
92 M/S	√	√	N/A	√	√	√
272 M/S	√	√	N/A	√	NO	√
312 M/S	√	√	N/A	NO	√	√
304 M/S	√	√	N/A	√	NO	√
643 M/S	√	√	N/A	√	√	√
768 M/S	√	√	N/A	√	NO	√
791M/S	√	√	N/A	NO	√	√
1664M/S	√	√	N/A	NO	NO	√

Attachment E

U.S. DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE
INTERNATIONAL PROGRAMS

FOREIGN COUNTRY LABORATORY REVIEW

REVIEW DATE	NAME OF FOREIGN LABORATORY
5/17/01	Instituti Zooproficlattici Sperimentali (IZS)

FOREIGN GOV'T AGENCY	CITY & COUNTRY	ADDRESS OF LABORATORY
Picmonte - Liguria	TORINO-ITALY	Sede Centrale,10154 Torion, Via Bologna, 148

NAME OF REVIEWER	NAME OF FOREIGN OFFICIAL
Dr. Faiz R. Choudry	Dr. Cantini Cortellezzi , Ptof. Direttore

	REVIEW ITEMS	ITEM #	EVALUATION CODE	100	111	300	400	500	923	800	203	200	S/V		
	Residue Code/Name ▶														
SAMPLING PROCEDURES	Sample Handling	01		A	A	A	A	A	A	A	A	A	A		
	Sampling Frequency	02		A	A	A	A	A	A	A	A	A	A		
	Timely Analyses	03		A	A	A	A	A	A	A	A	A	A		
	Compositing Procedure	04		O	O	O	O	O	O	O	O	O	O		
	Interpret Comp Data	05		O	O	O	O	O	O	O	O	O	O		
	Data Reporting	06		A	A	A	A	A	A	A	A	A	A		
ANALYTICAL PROCEDURES	Acceptable Method	07		A	A	A	A	A	A	A	A	A	A		
	Correct Tissue(s)	08		A	A	A	A	A	A	A	A	A	A		
	Equipment Operation	09		A	A	A	A	A	A	A	A	A	A		
	Instrument Printouts	10		A	A	A	A	A	A	A	A	A	O		
QUALITY ASSURANCE PROCEDURES	Minimum Detection Levels	11		A	A	A	A	A	A	A	A	A	O		
	Recovery Frequency	12		A	A	A	A	A	A	A	A	A	O		
	Percent Recovery	13		A	A	A	A	A	A	A	A	A	O		
	Check Sample Frequency	14		A	A	A	A	A	A	A	A	A	A		
	All analyst w/Check Samples	15		A	A	A	A	A	A	A	A	A	A		
	Corrective Actions	16		A	A	A	A	A	A	A	A	A	A		
	International Check Samples	17		A	A	A	A	A	A	A	A	A	A		
REVIEW PROCEDURES	Corrected Prior Deficiencies	18	EVAL. CODE	N	N	N	N	N	N	N	N	N	N		
OTHER REVIEW		19	EVAL. CODE												
		20	EVAL. CODE												

SIGNATURE OF REVIEWER

DATE

Designed on FormFlow Software

LAB #1

U.S. DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE
INTERNATIONAL PROGRAMS

FOREIGN COUNTRY LABORATORY REVIEW

REVIEW DATE: 5-9-01

NAME OF FOREIGN LABORATORY: Istituti Zooprofilattici Region Lazio - Toscana — Rome —

FOREIGN GOV'T AGENCY:

CITY & COUNTRY: Rome, Italy

ADDRESS OF LABORATORY: Sede Centrale: 00178 CAPANNELLE (ROMA) Via Appia Nuova, 1411 Tel. 06/79099-79099400 Direttore f.f.: Dott. AUTORINO Gianluca

NAME OF REVIEWER: Geraldine M. Ransom

NAME OF FOREIGN OFFICIAL: Dr. Giuliana Fontanelli, Director, Food Microbiology

	Residue Code/Name ▶																	
SAMPLING PROCEDURES	REVIEW ITEMS	ITEM #	EVALUATION CODE															
	Sample Handling	01		✓ OK														
	Sampling Frequency	02		NA														
	Timely Analyses	03		✓ OK														
	Compositing Procedure	04		NA														
	Interpret Comp Data	05		✓ OK														
	Data Reporting	06		✓ OK														
ANALYTICAL PROCEDURES	Acceptable Method	07	EVALUATION CODE	See comments														
	Correct Tissue(s)	08		NA														
	Equipment Operation	09		✓ OK														
	Instrument Printouts	10		✓ OK														
QUALITY ASSURANCE PROCEDURES	Minimum Detection Levels	11	EVALUATION CODE	NA														
	Recovery Frequency	12		NA														
	Percent Recovery	13		NA														
	Check Sample Frequency	14		See comments														
	All analyst w/Check Samples	15																
	Corrective Actions	16		✓ Yes														
	International Check Samples	17		NO														
REVIEW PROCEDURES	Corrected Prior Deficiencies	18	EVAL. CODE															
OTHER REVIEW		19	EVAL. CODE															
		20																

SIGNATURE OF REVIEWER: Geraldine Ransom

DATE: 6-11-01

FSIS FORM 9520-4 (9/96)

Designed on FormFlow Software

LAB #2

U.S. DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE
INTERNATIONAL PROGRAMS

FOREIGN COUNTRY LABORATORY REVIEW

REVIEW DATE	NAME OF FOREIGN LABORATORY
5-11-01	Istituti Zooprofilattici Region Umbria - Marche - ANCONA -

FOREIGN GOV'T AGENCY	CITY & COUNTRY	ADDRESS OF LABORATORY
	Ancona, Italy	Sezioni Diagnostiche: 60100 ANCONA Via Cupa di Posatora 3 Tel. 071/41760-42991 - Fax 4: Dirigente: Dott. BACCHIOCC

NAME OF REVIEWER	NAME OF FOREIGN OFFICIAL
Geraldine M. Ransom	DR. Donatella Ottaviani, Director, Food Microbiology

	REVIEW ITEMS	ITEM #	EVALUATION CODE	Residue Code/Name ▶												
SAMPLING PROCEDURES	Sample Handling	01		✓ OK												
	Sampling Frequency	02		NA												
	Timely Analyses	03		✓ OK												
	Compositing Procedure	04		NA												
	Interpret Comp Data	05		✓ OK												
	Data Reporting	06		✓ OK												
ANALYTICAL PROCEDURES	Acceptable Method	07	EVALUATION CODE	see comments												
	Correct Tissue(s)	08		NA												
	Equipment Operation	09		✓ OK												
	Instrument Printouts	10		✓ OK												
QUALITY ASSURANCE PROCEDURES	Minimum Detection Levels	11	EVALUATION CODE	NA												
	Recovery Frequency	12		NA												
	Percent Recovery	13		NA												
	Check Sample Frequency	14		✓ OK												
	All analyst w/Check Samples	15														
	Corrective Actions	16		✓ OK												
	International Check Samples	17		NO												
REVIEW PROCEDURES	Corrected Prior Deficiencies	18	EVAL. CODE													
OTHER REVIEW		19	EVAL. CODE													
		20														

SIGNATURE OF REVIEWER: Geraldine M. Ransom

DATE: 6-11-01

Lab #3

U.S. DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE
INTERNATIONAL PROGRAMS

FOREIGN COUNTRY LABORATORY REVIEW

REVIEW DATE: 5-14-01

NAME OF FOREIGN LABORATORY: Istituti Zooprofilattici Region Umbria-Marche - Perugia -

FOREIGN GOV'T AGENCY:

CITY & COUNTRY: Perugia, Italy

ADDRESS OF LABORATORY: Sede Centrale: 06100PERUGIA Via G. Salvemini 1 Tel. 075/3431 (10 linee) - Fax: Direttore: Dott. PETRACCA G

NAME OF REVIEWER: Geraldine M. Ransom

NAME OF FOREIGN OFFICIAL: DR. Stefania Scuota

Residue Code/Name ▶

	REVIEW ITEMS	ITEM #	EVALUATION CODE	
SAMPLING PROCEDURES	Sample Handling	01		✓ OK
	Sampling Frequency	02		NA
	Timely Analyses	03		✓ OK
	Compositing Procedure	04		NA
	Interpret Comp Data	05		✓ OK
	Data Reporting	06		✓ OK
ANALYTICAL PROCEDURES	Acceptable Method	07		see comments
	Correct Tissue(s)	08		NA
	Equipment Operation	09		✓ OK
	Instrument Printouts	10		✓ OK
QUALITY ASSURANCE PROCEDURES	Minimum Detection Levels	11		NA
	Recovery Frequency	12		NA
	Percent Recovery	13		NA
	Check Sample Frequency	14		✓ OK
	All analyst w/Check Samples	15		✓ yes
	Corrective Actions	16		✓ yes
	International Check Samples	17		NO
REVIEW PROCEDURES	Corrected Prior Deficiencies	18	EVAL. CODE	
OTHER REVIEW		19	EVAL. CODE	
		20	EVAL. CODE	

SIGNATURE OF REVIEWER

DATE: 6-11-01

LAB #4

U.S. DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE
INTERNATIONAL PROGRAMS

FOREIGN COUNTRY LABORATORY REVIEW

REVIEW DATE: 5-15-01

NAME OF FOREIGN LABORATORY: Istituti Zooprofilattici Region Lazio + Toscana Florence

FOREIGN GOV'T AGENCY:

CITY & COUNTRY: Florence, Italy

ADDRESS OF LABORATORY:

NAME OF REVIEWER: Geraldine Ransom

NAME OF FOREIGN OFFICIAL: DR. Paola Marconi: Director Food Microbiology Laboratory

Residue Code/Name ▶

	REVIEW ITEMS	ITEM #	EVALUATION CODE
SAMPLING PROCEDURES	Sample Handling	01	√ OK
	Sampling Frequency	02	NA
	Timely Analyses	03	√ OK
	Compositing Procedure	04	NA
	Interpret Comp Data	05	√ OK
	Data Reporting	06	√ OK
ANALYTICAL PROCEDURES	Acceptable Method	07	See comments
	Correct Tissue(s)	08	NA
	Equipment Operation	09	√ OK
	Instrument Printouts	10	√ OK
QUALITY ASSURANCE PROCEDURES	Minimum Detection Levels	11	NA
	Recovery Frequency	12	NA
	Percent Recovery	13	NA
	Check Sample Frequency	14	See comments
	All analyst w/Check Samples	15	
	Corrective Actions	16	√ OK
	International Check Samples	17	NO
REVIEW PROCEDURES	Corrected Prior Deficiencies	18	EVAL. CODE
OTHER REVIEW		19	EVAL. CODE
		20	EVAL. CODE

SIGNATURE OF REVIEWER

DATE

FSIS FORM 9620-4 (9/96)

Designed on FormFlow Software

LAB #5

U.S. DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE
INTERNATIONAL PROGRAMS

FOREIGN COUNTRY LABORATORY REVIEW

REVIEW DATE: 5-16-01

NAME OF FOREIGN LABORATORY: Istituti Zooprofilattici Lombardia, Region Emilia-Romagna -Brescia-

FOREIGN GOV'T AGENCY:

CITY & COUNTRY: Brescia, Italy

ADDRESS OF LABORATORY: Sede Centrale: 25124 BRESCIA Via A. Bianchi, 7 Tel. 030/22901 - Fax 225613/2425251 Direttore: Prof. LODETTI Ezio

NAME OF REVIEWER: Geroldine M. Ransom

NAME OF FOREIGN OFFICIAL: DR. Franco Paterlini: Director Food Microbiology Laboratory

	Residue Code/Name ▶															
	REVIEW ITEMS	ITEM #	EVALUATION CODE													
SAMPLING PROCEDURES	Sample Handling	01		V OK												
	Sampling Frequency	02		NA												
	Timely Analyses	03		V OK												
	Compositing Procedure	04		NA												
	Interpret Comp Data	05		V OK												
	Data Reporting	06		V OK												
ANALYTICAL PROCEDURES	Acceptable Method	07	EVALUATION CODE	See comments												
	Correct Tissue(s)	08		NA												
	Equipment Operation	09		V OK												
	Instrument Printouts	10		V OK												
QUALITY ASSURANCE PROCEDURES	Minimum Detection Levels	11	EVALUATION CODE	NA												
	Recovery Frequency	12		NA												
	Percent Recovery	13		NA												
	Check Sample Frequency	14		See comments												
	All analyst w/Check Samples	15														
	Corrective Actions	16		V OK												
	International Check Samples	17		NO												
REVIEW PROCEDURES	Corrected Prior Deficiencies	18	EVAL. CODE													
OTHER REVIEW		19	EVAL. CODE													
		20														

SIGNATURE OF REVIEWER

DATE

LAB #6

U.S. DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE
INTERNATIONAL PROGRAMS

FOREIGN COUNTRY LABORATORY REVIEW

REVIEW DATE: 5/7-01

NAME OF FOREIGN LABORATORY: Istituti Zooprofilattici Region Piemonte-Liguria Valle D'Aosta - Torino

FOREIGN GOV'T AGENCY:

CITY & COUNTRY: Torino, Italy

ADDRESS OF LABORATORY: Sede Centrale: 10154 TORINO Via Bologna, 148 Tel. 011/26861 - Fax 2487770 Direttore: Prof. CANTINI CORTELLEZZI Giulio

NAME OF REVIEWER: Geraldine M. Ransom

NAME OF FOREIGN OFFICIAL: Dr./ De castelli: Director Food Microbiology Laboratory

	Residue Code/Name ▶																	
SAMPLING PROCEDURES	REVIEW ITEMS	ITEM #	EVALUATION CODE	✓														
	Sample Handling	01		OK														
	Sampling Frequency	02		NA														
	Timely Analyses	03		✓ OK														
	Compositing Procedure	04		NA														
	Interpret Comp Data	05		✓ OK														
	Data Reporting	06		✓ OK														
ANALYTICAL PROCEDURES	Acceptable Method	07	EVALUATION CODE	See comments														
	Correct Tissue(s)	08		NA														
	Equipment Operation	09		✓ OK														
	Instrument Printouts	10		✓ OK														
QUALITY ASSURANCE PROCEDURES	Minimum Detection Levels	11	EVALUATION CODE	NA														
	Recovery Frequency	12		NA														
	Percent Recovery	13		NA														
	Check Sample Frequency	14		✓ OK														
	All analyst w/Check Samples	15		✓ OK														
	Corrective Actions	16		✓ OK														
	International Check Samples	17		NO														
REVIEW PROCEDURES	Corrected Prior Deficiencies	18	EVAL. CODE															
OTHER REVIEW		19	EVAL. CODE															
		20																

SIGNATURE OF REVIEWER

DATE

LAB #7

U.S. DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE
INTERNATIONAL PROGRAMS

FOREIGN COUNTRY LABORATORY REVIEW

REVIEW DATE: 5-21-01

NAME OF FOREIGN LABORATORY: Istituto Superiore di Sanita (ISS)

FOREIGN GOV'T AGENCY: Italian National Health Service

CITY & COUNTRY: Rome, Italy

ADDRESS OF LABORATORY: Viale Regina Elena, 299 00161 Rome, Italy

NAME OF REVIEWER:

NAME OF FOREIGN OFFICIAL: Dr. Paolo Aureli, Director Food Microbiology Laboratory

	REVIEW ITEMS	ITEM #	EVALUATION CODE	Residue Code/Name ▶
SAMPLING PROCEDURES	Sample Handling	01		V OK
	Sampling Frequency	02		NA
	Timely Analyses	03		V OK
	Compositing Procedure	04		NA
	Interpret Comp Data	05		V OK
	Data Reporting	06		V OK
ANALYTICAL PROCEDURES	Acceptable Method	07		see comments
	Correct Tissue(s)	08		NA
	Equipment Operation	09		V OK
	Instrument Printouts	10		V OK
QUALITY ASSURANCE PROCEDURES	Minimum Detection Levels	11		NA
	Recovery Frequency	12		NA
	Percent Recovery	13		NA
	Check Sample Frequency	14		see comments
	All analyst w/Check Samples	16		
	Corrective Actions	16		
	International Check Samples	17		NO
REVIEW PROCEDURES	Corrected Prior Deficiencies	18	EVAL. CODE	
OTHER REVIEW		19	EVAL. CODE	
		20	EVAL. CODE	

SIGNATURE OF REVIEWER

DATE

Attachment F

U.S. DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE
INTERNATIONAL PROGRAMS

FOREIGN PLANT REVIEW FORM

REVIEW DATE	ESTABLISHMENT NO. AND NAME	CITY
5/22/01	Est.0005 L Levoni S.P.A.	Castelluchhio
		COUNTRY: Italy

NAME OF REVIEWER	NAME OF FOREIGN OFFICIAL	EVALUATION
M. Ghias Mughal, DVM	Dr. Minelli	☐ Acceptable ☒ Acceptable/ Re-review ☐ Unacceptable

CODES (Give an appropriate code for each review item listed below)
A = Acceptable M = Marginally Acceptable U = Unacceptable N = Not Reviewed O = Does not apply

1. CONTAMINATION CONTROL		Cross contamination prevention	28 A	Formulations	55 A
(a) BASIC ESTABLISHMENT FACILITIES		Equipment Sanitizing	29 A	Packaging materials	56 A
Water potability records	01 A	Product handling and storage	30 A	Laboratory confirmation	57 A
Chlorination procedures	02 A	Product reconditioning	31 U	Label approvals	58 A
Back siphonage prevention	03 A	Product transportation	32 A	Special label claims	59 A
Hand washing facilities	04 A	**(d) ESTABLISHMENT SANITATION PROGRAM**		Inspector monitoring	60 A
Sanitizers	05 A	Effective maintenance program	33 A	Processing schedules	61 A
Establishments separation	06 A	Preoperational sanitation	34 A	Processing equipment	62 A
Pest --no evidence	07 A	Operational sanitation	35 A	Processing records	63 A
Pest control program	08 A	Waste disposal	36 A	Empty can inspection	64 O
Pest control monitoring	09 A	**2. DISEASE CONTROL**		Filling procedures	65 O
Temperature control	10 A	Animal identification	37 O	Container closure exam	66 O
Lighting	11 A	Antemortem inspec. procedures	38 O	Interim container handling	67 O
Operations work space	12 A	Antemortem dispositions	39 O	Post-processing handling	68 O
Inspector work space	13 O	Humane Slaughter	40 O	Incubation procedures	69 O
Ventilation	14 A	Postmortem inspec. procedures	41 O	Process. defect actions -- plant	70 O
Facilities approval	15 A	Postmortem dispositions	42 O	Processing control -- inspection	71 A
Equipment approval	16 A	Condemned product control	43 N	**5. COMPLIANCE/ECON. FRAUD CONTROL**	
(b) CONDITION OF FACILITIES EQUIPMENT		Restricted product control	44 A	Export product identification	72 A
Over-product ceilings	17 A	Returned and rework product	45 N	Inspector verification	73 A
Over-product equipment	18 M	**3. RESIDUE CONTROL**		Export certificates	74 A
Product contact equipment	19 U	Residue program compliance	46 A	Single standard	75 A
Other product areas *(inside)*	20 M	Sampling procedures	47 A	Inspection supervision	76 A
Dry storage areas	21 U	Residue reporting procedures	48 A	Control of security items	77 A
Antemortem facilities	22 O	Approval of chemicals, etc.	49 A	Shipment security	78 A
Welfare facilities	23 A	Storage and use of chemicals	50 A	Species verification	79 A
Outside premises	24 A	**4. PROCESSED PRODUCT CONTROL**		"Equal to" status	80 A
(c) PRODUCT PROTECTION & HANDLING		Pre-boning trim	51 O	Imports	81 A
Personal dress and habits	25 A	Boneless meat reinspection	52 O	HACCP...See Attachment C	M
Personal hygiene practices	26 A	Ingredients identification	53 A		
Sanitary dressing procedures	27 A	Control of restricted ingredients	54 A		

U.S. DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE
INTERNATIONAL PROGRAMS

FOREIGN PLANT REVIEW FORM

REVIEW DATE: 05/31/01

ESTABLISHMENT NO. AND NAME: Est. 17-L `Star Stabilimento Alimentare S.P.A.

CITY: Agrate Brianza (MI)

COUNTRY: ITALY

NAME OF REVIEWER: Dr. Faiz R. Choudry

NAME OF FOREIGN OFFICIAL: Dr. Galli Marco, Supervisor 7 Dr. Castoldi

EVALUATION: ☐ Acceptable ☒ Acceptable/ Re-review ☐ Unacceptable

CODES (Give an appropriate code for each review item listed below)
A = Acceptable M = Marginally Acceptable U = Unacceptable N = Not Reviewed O = Does not apply

1. CONTAMINATION CONTROL		Cross contamination prevention	28 A	Formulations	55 A
(a) BASIC ESTABLISHMENT FACILITIES		Equipment Sanitizing	29 A	Packaging materials	56 A
Water potability records	01 A	Product handling and storage	30 A	Laboratory confirmation	57 A
Chlorination procedures	02 A	Product reconditioning	31 A	Label approvals	58 A
Back siphonage prevention	03 A	Product transportation	32 A	Special label claims	59 O
Hand washing facilities	04 A	**(d) ESTABLISHMENT SANITATION PROGRAM**		Inspector monitoring	60 A
Sanitizers	05 A	Effective maintenance program	33 A	Processing schedules	61 A
Establishments separation	06 A	Preoperational sanitation	34 M	Processing equipment	62 A
Pest --no evidence	07 M	Operational sanitation	35 A	Processing records	63 A
Pest control program	08 A	Waste disposal	36 A	Empty can inspection	64 A
Pest control monitoring	09 A	**2. DISEASE CONTROL**		Filling procedures	65 A
Temperature control	10 A	Animal identification	37 O	Container closure exam	66 A
Lighting	11 A	Antemortem inspec. procedures	38 O	Interim container handling	67 A
Operations work space	12 A	Antemortem dispositions	39 O	Post-processing handling	68 A
Inspector work space	13 O	Humane Slaughter	40 O	Incubation procedures	69 A
Ventilation	14 A	Postmortem inspec. procedures	41 O	Process. defect actions -- plant	70 A
Facilities approval	15 A	Postmortem dispositions	42 O	Processing control -- inspection	71 A
Equipment approval	16 A	Condemned product control	43 A	**5. COMPLIANCE/ECON. FRAUD CONTROL**	
(b) CONDITION OF FACILITIES EQUIPMENT		Restricted product control	44 O	Export product identification	72 A
Over-product ceilings	17 A	Returned and rework product	45 A	Inspector verification	73 A
Over-product equipment	18 M	**3. RESIDUE CONTROL**		Export certificates	74 A
Product contact equipment	19 U	Residue program compliance	46 O	Single standard	75 A
Other product areas *(inside)*	20 A	Sampling procedures	47 O	Inspection supervision	76 A
Dry storage areas	21 A	Residue reporting procedures	48 O	Control of security items	77 A
Antemortem facilities	22 O	Approval of chemicals, etc.	49 A	Shipment security	78 A
Welfare facilities	23 A	Storage and use of chemicals	50 A	Species verification	79 A
Outside premises	24 A	**4 PROCESSED PRODUCT CONTROL**		"Equal to" status	80 A
(c) PRODUCT PROTECTION & HANDLING		Pre-boning trim	51 O	Imports	81 A
Personal dress and habits	25 A	Boneless meat reinspection	52 O		
Personal hygiene practices	26 A	Ingredients identification	53 A		
Sanitary dressing procedures	27 O	Control of restricted ingredients	54 A	COMMENTS MADE ON REVERSE	

U.S. DEPARTMENT OF AGRICULTURE FOOD SAFETY AND INSPECTION SERVICE INTERNATIONAL PROGRAMS **FOREIGN PLANT REVIEW FORM**	REVIEW DATE 05/29/01	ESTABLISHMENT NO. AND NAME Est. 31-L Giuseppecitterio Salumificio S.P.A.	CITY Ro (MI) COUNTRY ITALY
NAME OF REVIEWER Dr. Faiz R. Choudry	NAME OF FOREIGN OFFICIAL Dr. Enrico Melgrati & Dr. Castoldi	EVALUATION ☒ Acceptable ☐ Acceptable/ Re-review ☐ Unacceptable	

CODES (Give an appropriate code for each review item listed below)
A = Acceptable M = Marginally Acceptable U = Unacceptable N = Not Reviewed O = Does not apply

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(a) BASIC ESTABLISHMENT FACILITIES		Equipment Sanitizing	29 A	Packaging materials	56 A
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Sanitizers	05 A	Effective maintenance program	33 A	Processing schedules	61 A
Establishments separation	06 A	Preoperational sanitation	34 M	Processing equipment	62 A
Pest --no evidence	07 A	Operational sanitation	35 A	Processing records	63 A
Pest control program	08 A	Waste disposal	36 A	Empty can inspection	64 O
Pest control monitoring	09 A	**2. DISEASE CONTROL**		Filling procedures	65 O
Temperature control	10 A	Animal identification	37 O	Container closure exam	66 O
Lighting	11 A	Antemortem inspec. procedures	38 O	Interim container handling	67 O
Operations work space	12 A	Antemortem dispositions	39 O	Post-processing handling	68 O
Inspector work space	13 O	Humane Slaughter	40 O	Incubation procedures	69 O
Ventilation	14 A	Postmortem inspec. procedures	41 O	Process. defect actions -- plant	70 O
Facilities approval	15 A	Postmortem dispositions	42 O	Processing control -- inspection	71 A
Equipment approval	16 A	Condemned product control	43 A	**5. COMPLIANCE/ECON. FRAUD CONTROL**	
(b) CONDITION OF FACILITIES EQUIPMENT		Restricted product control	44 O	Export product identification	72 A
Over-product ceilings	17 A	Returned and rework product	45 N	Inspector verification	73 A
Over-product equipment	18 A	**3. RESIDUE CONTROL**		Export certificates	74 A
Product contact equipment	19 A	Residue program compliance	46 O	Single standard	75 A
Other product areas *(inside)*	20 A	Sampling procedures	47 O	Inspection supervision	76 A
Dry storage areas	21 A	Residue reporting procedures	48 O	Control of security items	77 A
Antemortem facilities	22 O	Approval of chemicals, etc.	49 A	Shipment security	78 A
Welfare facilities	23 A	Storage and use of chemicals	50 A	Species verification	79 A
Outside premises	24 A	**4. PROCESSED PRODUCT CONTROL**		"Equal to" status	80 A
(c) PRODUCT PROTECTION & HANDLING		Pre-boning trim	51 O	Imports	81 A
Personal dress and habits	25 A	Boneless meat reinspection	52 O		
Personal hygiene practices	26 A	Ingredients identification	53 A		
Sanitary dressing procedures	27 O	Control of restricted ingredients	54 A	**COMMENTS MADE ON REVERSE**	

U.S. DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE
INTERNATIONAL PROGRAMS

FOREIGN PLANT REVIEW FORM

REVIEW DATE	ESTABLISHMENT NO. AND NAME	CITY
5/30/01	Est. 0041/L Alcisa S.p. A.	Zola, Predosa
		COUNTRY Italy

NAME OF REVIEWER	NAME OF FOREIGN OFFICIAL	EVALUATION
M. Ghias Mughal, DVM	Dr. Milana	☐ Acceptable ☒ Acceptable/ Re-review ☐ Unacceptable

CODES (Give an appropriate code for each review item listed below)
A = Acceptable M = Marginally Acceptable U = Unacceptable N = Not Reviewed O = Does not apply

1. CONTAMINATION CONTROL		Cross contamination prevention	28 A	Formulations	55 A
(a) BASIC ESTABLISHMENT FACILITIES		Equipment Sanitizing	29 A	Packaging materials	56 A
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Establishments separation	06 A	Preoperational sanitation	34 A	Processing equipment	62 A
Pest --no evidence	07 A	Operational sanitation	35 A	Processing records	63 A
Pest control program	08 A	Waste disposal	36 A	Empty can inspection	64 O
Pest control monitoring	09 A	**2. DISEASE CONTROL**		Filling procedures	65 O
Temperature control	10 A	Animal identification	37 O	Container closure exam	66 O
Lighting	11 A	Antemortem inspec. procedures	38 O	Interim container handling	67 O
Operations work space	12 A	Antemortem dispositions	39 O	Post-processing handling	68 O
Inspector work space	13 O	Humane Slaughter	40 O	Incubation procedures	69 O
Ventilation	14 A	Postmortem inspec. procedures	41 O	Process. defect actions -- plant	70 O
Facilities approval	15 A	Postmortem dispositions	42 O	Processing control -- inspection	71 A
Equipment approval	16 A	Condemned product control	43 U	**5. COMPLIANCE/ECON. FRAUD CONTROL**	
(b) CONDITION OF FACILITIES EQUIPMENT		Restricted product control	44 A	Export product identification	72 A
Over-product ceilings	17 U	Returned and rework product	45 N	Inspector verification	73 A
Over-product equipment	18 A	**3. RESIDUE CONTROL**		Export certificates	74 A
Product contact equipment	19 U	Residue program compliance	46 A	Single standard	75 A
Other product areas *(inside)*	20 M	Sampling procedures	47 A	Inspection supervision	76 A
Dry storage areas	21 A	Residue reporting procedures	48 A	Control of security items	77 A
Antemortem facilities	22 O	Approval of chemicals, etc.	49 A	Shipment security	78 A
Welfare facilities	23 A	Storage and use of chemicals	50 A	Species verification	79 A
Outside premises	24 A	**4. PROCESSED PRODUCT CONTROL**		"Equal to" status	80 A
(c) PRODUCT PROTECTION & HANDLING		Pre-boning trim	51 O	Imports	81 A
Personal dress and habits	25 A	Boneless meat reinspection	52 O		
Personal hygiene practices	26 A	Ingredients identification	53 A		
Sanitary dressing procedures	27 A	Control of restricted ingredients	54 A		

U.S. DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE
INTERNATIONAL PROGRAMS

FOREIGN PLANT REVIEW FORM

REVIEW DATE	ESTABLISHMENT NO. AND NAME	CITY
05/23/01	Est. 92 Fumagalli Industria Alimentare S.P. A.	Tavernerio
		COUNTRY ITALY

NAME OF REVIEWER	NAME OF FOREIGN OFFICIAL	EVALUATION
Dr. Faiz R. Choudry	Dr. Gridavilla, Dr. Noe, & Dr. Castoldi	☐ Acceptable ☐ Acceptable/ Re-review ☒ Unacceptable

CODES (Give an appropriate code for each review item listed below)
A = Acceptable M = Marginally Acceptable U = Unacceptable N = Not Reviewed O = Does not apply

1. CONTAMINATION CONTROL		Cross contamination prevention	28 M	Formulations	55 O
(a) BASIC ESTABLISHMENT FACILITIES		Equipment Sanitizing	29 A	Packaging materials	56 A
Water potability records	01 A	Product handling and storage	30 A	Laboratory confirmation	57 O
Chlorination procedures	02 O	Product reconditioning	31 A	Label approvals	58 A
Back siphonage prevention	03 A	Product transportation	32 A	Special label claims	59 O
Hand washing facilities	04 A	**(d) ESTABLISHMENT SANITATION PROGRAM**		Inspector monitoring	60 A
Sanitizers	05 U	Effective maintenance program	33 A	Processing schedules	61 O
Establishments separation	06 A	Preoperational sanitation	34 U	Processing equipment	62 O
Pest -- no evidence	07 M	Operational sanitation	35 U	Processing records	63 O
Pest control program	08 A	Waste disposal	36 A	Empty can inspection	64 O
Pest control monitoring	09 A	**2. DISEASE CONTROL**		Filling procedures	65 O
Temperature control	10 A	Animal identification	37 A	Container closure exam	66 O
Lighting	11 A	Antemortem inspec. procedures	38 A	Interim container handling	67 O
Operations work space	12 A	Antemortem dispositions	39 A	Post-processing handling	68 O
Inspector work space	13 A	Humane Slaughter	40 A	Incubation procedures	69 O
Ventilation	14 A	Postmortem inspec. procedures	41 M	Process. defect actions -- plant	70 O
Facilities approval	15 A	Postmortem dispositions	42 A	Processing control -- inspection	71 A
Equipment approval	16 A	Condemned product control	43 M	**5. COMPLIANCE/ECON. FRAUD CONTROL**	
(b) CONDITION OF FACILITIES EQUIPMENT		Restricted product control	44 A	Export product identification	72 A
Over-product ceilings	17 U	Returned and rework product	45 N	Inspector verification	73 A
Over-product equipment	18 M	**3. RESIDUE CONTROL**		Export certificates	74 A
Product contact equipment	19 M	Residue program compliance	46 A	Single standard	75 A
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Antemortem facilities	22 A	Approval of chemicals, etc.	49 A	Shipment security	78 A
Welfare facilities	23 A	Storage and use of chemicals	50 A	Species verification	79 A
Outside premises	24 A	**4. PROCESSED PRODUCT CONTROL**		"Equal to" status	80 U
(c) PRODUCT PROTECTION & HANDLING		Pre-boning trim	51 A	Imports	81 A
Personal dress and habits	25 A	Boneless meat reinspection	52 O	HACCP	U
Personal hygiene practices	26 A	Ingredients identification	53 O		
Sanitary dressing procedures	27 A	Control of restricted ingredients	54 O	COMMENTS MADE ON REVERSE	

U.S. DEPARTMENT OF AGRICULTURE FOOD SAFETY AND INSPECTION SERVICE INTERNATIONAL PROGRAMS **FOREIGN PLANT REVIEW FORM**	REVIEW DATE 5/28/01	ESTABLISHMENT NO. AND NAME Est. 172/L Unibon Salumi Soc. Coop. A.r.L.	CITY Reggio Emilia COUNTRY Italy
NAME OF REVIEWER M. Ghias Mughal, DVM	NAME OF FOREIGN OFFICIAL Dr.Moscardini	EVALUATION [X] Acceptable [ ] Acceptable/ Re-review [ ] Unacceptable	

CODES (Give an appropriate code for each review item listed below)

A = Acceptable M = Marginally Acceptable U = Unacceptable N = Not Reviewed O = Does not apply

1. CONTAMINATION CONTROL		Cross contamination prevention	28 A	Formulations	55 A
(a) BASIC ESTABLISHMENT FACILITIES		Equipment Sanitizing	29 A	Packaging materials	56 A
Water potability records	01 A	Product handling and storage	30 A	Laboratory confirmation	57 A
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Hand washing facilities	04 A	**(d) ESTABLISHMENT SANITATION PROGRAM**		Inspector monitoring	60 A
Sanitizers	05 A	Effective maintenance program	33 A	Processing schedules	61 A
Establishments separation	06 A	Preoperational sanitation	34 A	Processing equipment	62 A
Pest --no evidence	07 A	Operational sanitation	35 A	Processing records	63 A
Pest control program	08 A	Waste disposal	36 A	Empty can inspection	64 O
Pest control monitoring	09 A	**2. DISEASE CONTROL**		Filling procedures	65 O
Temperature control	10 A	Animal identification	37 O	Container closure exam	66 O
Lighting	11 A	Antemortem inspec. procedures	38 O	Interim container handling	67 O
Operations work space	12 A	Antemortem dispositions	39 O	Post-processing handling	68 O
Inspector work space	13 O	Humane Slaughter	40 O	Incubation procedures	69 O
Ventilation	14 A	Postmortem inspec. procedures	41 O	Process. defect actions -- plant	70 O
Facilities approval	15 A	Postmortem dispositions	42 O	Processing control -- inspection	71 A
Equipment approval	16 A	Condemned product control	43 U	**5. COMPLIANCE/ECON. FRAUD CONTROL**	
(b) CONDITION OF FACILITIES EQUIPMENT		Restricted product control	44 A	Export product identification	72 A
Over-product ceilings	17 A	Returned and rework product	45 N	Inspector verification	73 A
Over-product equipment	18 A	**3. RESIDUE CONTROL**		Export certificates	74 A
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Welfare facilities	23 A	Storage and use of chemicals	50 A	Species verification	79 A
Outside premises	24 A	**4. PROCESSED PRODUCT CONTROL**		"Equal to" status	80 A
(c) PRODUCT PROTECTION & HANDLING		Pre-boning trim	51 O	Imports	81 A
Personal dress and habits	25 A	Boneless meat reinspection	52 O		
Personal hygiene practices	26 A	Ingredients identification	53 A		
Sanitary dressing procedures	27 A	Control of restricted ingredients	54 A		

U.S. DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE
INTERNATIONAL PROGRAMS

FOREIGN PLANT REVIEW FORM

REVIEW DATE	ESTABLISHMENT NO. AND NAME	CITY
5/21/01	Est.0205 L Principe Di San Daniele S.p.A.	San Daniele D Fruili
		COUNTRY: Italy

NAME OF REVIEWER	NAME OF FOREIGN OFFICIAL	EVALUATION
M. Ghias Mughal, DVM	Dr. Caliz	☐ Acceptable ☒ Acceptable/ Re-review ☐ Unacceptable

CODES (Give an appropriate code for each review item listed below)
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1. CONTAMINATION CONTROL		Cross contamination prevention	28 A	Formulations	55 A
(a) BASIC ESTABLISHMENT FACILITIES		Equipment Sanitizing	29 A	Packaging materials	56 A
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Hand washing facilities	04 A	**(d) ESTABLISHMENT SANITATION PROGRAM**		Inspector monitoring	60 A
Sanitizers	05 A	Effective maintenance program	33 A	Processing schedules	61 A
Establishments separation	06 A	Preoperational sanitation	34 A	Processing equipment	62 A
Pest --no evidence	07 U	Operational sanitation	35 A	Processing records	63 A
Pest control program	08 A	Waste disposal	36 A	Empty can inspection	64 O
Pest control monitoring	09 A	**2. DISEASE CONTROL**		Filling procedures	65 O
Temperature control	10 A	Animal identification	37 O	Container closure exam	66 O
Lighting	11 A	Antemortem inspec. procedures	38 O	Interim container handling	67 O
Operations work space	12 A	Antemortem dispositions	39 O	Post-processing handling	68 O
Inspector work space	13 O	Humane Slaughter	40 O	Incubation procedures	69 O
Ventilation	14 A	Postmortem inspec. procedures	41 O	Process. defect actions -- plant	70 O
Facilities approval	15 A	Postmortem dispositions	42 O	Processing control -- inspection	71 A
Equipment approval	16 A	Condemned product control	43 U	**5. COMPLIANCE/ECON. FRAUD CONTROL**	
(b) CONDITION OF FACILITIES EQUIPMENT		Restricted product control	44 A	Export product identification	72 A
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Outside premises	24 A	**4. PROCESSED PRODUCT CONTROL**		"Equal to" status	80 A
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Personal hygiene practices	26 A	Ingredients identification	53 A		
Sanitary dressing procedures	27 A	Control of restricted ingredients	54 A		

U.S. DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE
INTERNATIONAL PROGRAMS

FOREIGN PLANT REVIEW FORM

REVIEW DATE	ESTABLISHMENT NO. AND NAME	CITY
05/24/01	Est. 240-L Salumificio Goldoni Domenico E.C S.P.A.	Langhirano (PR)
		COUNTRY ITALY

NAME OF REVIEWER	NAME OF FOREIGN OFFICIAL	EVALUATION
Dr. Faiz R. Choudry	Dr. Cozzolino, Supervisor	[X] Acceptable [ ] Acceptable/ Re-review [ ] Unacceptable

CODES (Give an appropriate code for each review item listed below)
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1. CONTAMINATION CONTROL		Cross contamination prevention	28 A	Formulations	55 A
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U.S. DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE
INTERNATIONAL PROGRAMS

FOREIGN PLANT REVIEW FORM

REVIEW DATE	ESTABLISHMENT NO. AND NAME	CITY
05/09/01	Est. 272-M/S Cesare Fiorucci S.P.A.	Santa Palomba
		COUNTRY: ITALY

NAME OF REVIEWER	NAME OF FOREIGN OFFICIAL	EVALUATION
Dr. F. Choudry & Dr. G. Mughal	Dr.Claudio Principi & Dr. Adriano Giorgioni	☐ Acceptable ☐ Acceptable/ Re-review ☒ Unacceptable

CODES (Give an appropriate code for each review item listed below)
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1. CONTAMINATION CONTROL		Cross contamination prevention	28 U	Formulations	55 O
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Operations work space	12 A	Antemortem dispositions	39 A	Post-processing handling	68 O
Inspector work space	13 A	Humane Slaughter	40 A	Incubation procedures	69 O
Ventilation	14 A	Postmortem inspec. procedures	41 A	Process. defect actions -- plant	70 O
Facilities approval	15 A	Postmortem dispositions	42 A	Processing control -- inspection	71 A
Equipment approval	16 A	Condemned product control	43 A	**5. COMPLIANCE/ECON. FRAUD CONTROL**	
(b) CONDITION OF FACILITIES EQUIPMENT		Restricted product control	44 A	Export product identification	72 A
Over-product ceilings	17 U	Returned and rework product	45 A	Inspector verification	73 A
Over-product equipment	18 M	**3. RESIDUE CONTROL**		Export certificates	74 A
Product contact equipment	19 M	Residue program compliance	46 A	Single standard	75 A
Other product areas *(inside)*	20 A	Sampling procedures	47 A	Inspection supervision	76 A
Dry storage areas	21 A	Residue reporting procedures	48 A	Control of security items	77 A
Antemortem facilities	22 A	Approval of chemicals, etc.	49 A	Shipment security	78 A
Welfare facilities	23 A	Storage and use of chemicals	50 A	Species verification	79 O
Outside premises	24 A	**4. PROCESSED PRODUCT CONTROL**		"Equal to" status	80 U
(c) PRODUCT PROTECTION & HANDLING		Pre-boning trim	51 A	Imports	81 O
Personal dress and habits	25 A	Boneless meat reinspection	52 O	HACCP	U
Personal hygiene practices	26 A	Ingredients identification	53 O		
Sanitary dressing procedures	27 A	Control of restricted ingredients	54 O	COMMENTS MADE ON REVERSE	

U.S. DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE
INTERNATIONAL PROGRAMS

FOREIGN PLANT REVIEW FORM

REVIEW DATE	ESTABLISHMENT NO. AND NAME	CITY
05/08,09/01	Est. 272-L Fiorucci Cesare Salumificio S.P.A.	Pomezia
		COUNTRY: ITALY

NAME OF REVIEWER	NAME OF FOREIGN OFFICIAL	EVALUATION
Dr. F. Choudry & Dr. G. Mughal	Dr.Claudio Principi & Dr. Adriano Giorgioni	☐ Acceptable ☐ Acceptable/ Re-review ☒ Unacceptable

CODES (Give an appropriate code for each review item listed below)
A = Acceptable M = Marginally Acceptable U = Unacceptable N = Not Reviewed O = Does not apply

1. CONTAMINATION CONTROL		Cross contamination prevention	28 U	Formulations	55 A
(a) BASIC ESTABLISHMENT FACILITIES		Equipment Sanitizing	29 A	Packaging materials	56 A
Water potability records	01 A	Product handling and storage	30 M	Laboratory confirmation	57 O
Chlorination procedures	02 A	Product reconditioning	31 U	Label approvals	58 A
Back siphonage prevention	03 A	Product transportation	32 A	Special label claims	59 O
Hand washing facilities	04 A	**(d) ESTABLISHMENT SANITATION PROGRAM**		Inspector monitoring	60 A
Sanitizers	05 M	Effective maintenance program	33 M	Processing schedules	61 A
Establishments separation	06 A	Preoperational sanitation	34 U	Processing equipment	62 A
Pest --no evidence	07 M	Operational sanitation	35 U	Processing records	63 A
Pest control program	08 A	Waste disposal	36 A	Empty can inspection	64 O
Pest control monitoring	09 A	**2. DISEASE CONTROL**		Filling procedures	65 O
Temperature control	10 A	Animal identification	37 O	Container closure exam	66 O
Lighting	11 A	Antemortem inspec. procedures	38 O	Interim container handling	67 O
Operations work space	12 A	Antemortem dispositions	39 O	Post-processing handling	68 A
Inspector work space	13 O	Humane Slaughter	40 O	Incubation procedures	69 O
Ventilation	14 A	Postmortem inspec. procedures	41 O	Process. defect actions -- plant	70 A
Facilities approval	15 A	Postmortem dispositions	42 O	Processing control -- inspection	71 A
Equipment approval	16 A	Condemned product control	43 M	**5. COMPLIANCE/ECON. FRAUD CONTROL**	
(b) CONDITION OF FACILITIES EQUIPMENT		Restricted product control	44 A	Export product identification	72 A
Over-product ceilings	17 U	Returned and rework product	45 N	Inspector verification	73 A
Over-product equipment	18 M	**3. RESIDUE CONTROL**		Export certificates	74 A
Product contact equipment	19 U	Residue program compliance	46 O	Single standard	75 A
Other product areas *(inside)*	20 M	Sampling procedures	47 O	Inspection supervision	76 A
Dry storage areas	21 A	Residue reporting procedures	48 O	Control of security items	77 A
Antemortem facilities	22 O	Approval of chemicals, etc.	49 A	Shipment security	78 A
Welfare facilities	23 A	Storage and use of chemicals	50 A	Species verification	79 A
Outside premises	24 A	**4. PROCESSED PRODUCT CONTROL**		"Equal to" status	80 U
(c) PRODUCT PROTECTION & HANDLING		Pre-boning trim	51 O	Imports	81 A
Personal dress and habits	25 A	Boneless meat reinspection	52 O	HACCP	U
Personal hygiene practices	26 A	Ingredients identification	53 A		
Sanitary dressing procedures	27 O	Control of restricted ingredients	54 A	**COMMENTS MADE ON REVERSE**	

U.S. DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE
INTERNATIONAL PROGRAMS

FOREIGN PLANT REVIEW FORM

REVIEW DATE	ESTABLISHMENT NO. AND NAME	CITY
05/22/01	Est. 304 M/S Mec Carni S.P.A.	Macaria (MN) COUNTRY ITALY

NAME OF REVIEWER	NAME OF FOREIGN OFFICIAL	EVALUATION
Dr. Faiz R. Choudry	Dr. Pierantoni & Dr. Pasin, IIC	☐ Acceptable ☒ Acceptable/ Re-review ☐ Unacceptable

CODES (Give an appropriate code for each review item listed below)
A = Acceptable M = Marginally Acceptable U = Unacceptable N = Not Reviewed O = Does not apply

1. CONTAMINATION CONTROL		Cross contamination prevention	28 M	Formulations	55 O
(a) BASIC ESTABLISHMENT FACILITIES		Equipment Sanitizing	29 A	Packaging materials	56 A
Water potability records	01 A	Product handling and storage	30 A	Laboratory confirmation	57 O
Chlorination procedures	02 O	Product reconditioning	31 M	Label approvals	58 A
Back siphonage prevention	03 A	Product transportation	32 A	Special label claims	59 O
Hand washing facilities	04 A	**(d) ESTABLISHMENT SANITATION PROGRAM**		Inspector monitoring	60 A
Sanitizers	05 M	Effective maintenance program	33 A	Processing schedules	61 O
Establishments separation	06 A	Preoperational sanitation	34 M	Processing equipment	62 O
Pest --no evidence	07 M	Operational sanitation	35 A	Processing records	63 O
Pest control program	08 A	Waste disposal	36 A	Empty can inspection	64 O
Pest control monitoring	09 A	**2. DISEASE CONTROL**		Filling procedures	65 O
Temperature control	10 A	Animal identification	37 A	Container closure exam	66 O
Lighting	11 A	Antemortem inspec. procedures	38 A	Interim container handling	67 O
Operations work space	12 A	Antemortem dispositions	39 A	Post-processing handling	68 O
Inspector work space	13 A	Humane Slaughter	40 A	Incubation procedures	69 O
Ventilation	14 A	Postmortem inspec. procedures	41 A	Process. defect actions -- plant	70 O
Facilities approval	15 A	Postmortem dispositions	42 A	Processing control -- inspection	71 O
Equipment approval	16 A	Condemned product control	43 A	**5. COMPLIANCE/ECON. FRAUD CONTROL**	
(b) CONDITION OF FACILITIES EQUIPMENT		Restricted product control	44 A	Export product identification	72 A
Over-product ceilings	17 A	Returned and rework product	45 N	Inspector verification	73 A
Over-product equipment	18 A	**3. RESIDUE CONTROL**		Export certificates	74 A
Product contact equipment	19 M	Residue program compliance	46 A	Single standard	75 A
Other product areas *(inside)*	20 A	Sampling procedures	47 A	Inspection supervision	76 A
Dry storage areas	21 M	Residue reporting procedures	48 A	Control of security items	77 A
Antemortem facilities	22 A	Approval of chemicals, etc.	49 A	Shipment security	78 A
Welfare facilities	23 A	Storage and use of chemicals	50 A	Species verification	79 O
Outside premises	24 A	**4. PROCESSED PRODUCT CONTROL**		"Equal to" status	80 A
(c) PRODUCT PROTECTION & HANDLING		Pre-boning trim	51 A	Imports	81 O
Personal dress and habits	25 A	Boneless meat reinspection	52 O		
Personal hygiene practices	26 M	Ingredients identification	53 O		
Sanitary dressing procedures	27 A	Control of restricted ingredients	54 O	**COMMENTS MADE ON REVERSE**	

U.S. DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE
INTERNATIONAL PROGRAMS

FOREIGN PLANT REVIEW FORM

REVIEW DATE	ESTABLISHMENT NO. AND NAME	CITY
05/16/01	Est. 312-M/S Coop. Agricola Bertana S. r. L.	Castelverde
		COUNTRY ITALY

NAME OF REVIEWER	NAME OF FOREIGN OFFICIAL	EVALUATION
Dr. FAIZ R. CHOUDRY	Dr. Fucilli & Dr. Castoldi	☐ Acceptable ☒ Acceptable/ Re-review ☐ Unacceptable

CODES (Give an appropriate code for each review item listed below)
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1. CONTAMINATION CONTROL		Cross contamination prevention	28 A	Formulations	55 A
(a) BASIC ESTABLISHMENT FACILITIES		Equipment Sanitizing	29 A	Packaging materials	56 A
Water potability records	01 A	Product handling and storage	30 A	Laboratory confirmation	57 A
Chlorination procedures	02 A	Product reconditioning	31 A	Label approvals	58 A
Back siphonage prevention	03 A	Product transportation	32 A	Special label claims	59 A
Hand washing facilities	04 A	**(d) ESTABLISHMENT SANITATION PROGRAM**		Inspector monitoring	60 A
Sanitizers	05 A	Effective maintenance program	33 A	Processing schedules	61 A
Establishments separation	06 A	Preoperational sanitation	34 M	Processing equipment	62 A
Pest --no evidence	07 A	Operational sanitation	35 M	Processing records	63 A
Pest control program	08 A	Waste disposal	36 A	Empty can inspection	64 A
Pest control monitoring	09 A	**2. DISEASE CONTROL**		Filling procedures	65 A
Temperature control	10 A	Animal identification	37 A	Container closure exam	66 A
Lighting	11 A	Antemortem inspec. procedures	38 A	Interim container handling	67 A
Operations work space	12 A	Antemortem dispositions	39 A	Post-processing handling	68 A
Inspector work space	13 A	Humane Slaughter	40 A	Incubation procedures	69 A
Ventilation	14 A	Postmortem inspec. procedures	41 A	Process. defect actions -- plant	70 A
Facilities approval	15 A	Postmortem dispositions	42 A	Processing control -- inspection	71 A
Equipment approval	16 A	Condemned product control	43 A	**5. COMPLIANCE/ECON. FRAUD CONTROL**	
(b) CONDITION OF FACILITIES EQUIPMENT		Restricted product control	44 A	Export product identification	72 A
Over-product ceilings	17 A	Returned and rework product	45 A	Inspector verification	73 A
Over-product equipment	18 A	**3. RESIDUE CONTROL**		Export certificates	74 A
Product contact equipment	19 A	Residue program compliance	46 A	Single standard	75 A
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Antemortem facilities	22 A	Approval of chemicals, etc.	49 A	Shipment security	78 A
Welfare facilities	23 A	Storage and use of chemicals	50 A	Species verification	79 A
Outside premises	24 A	**4. PROCESSED PRODUCT CONTROL**		"Equal to" status	80 A
(c) PRODUCT PROTECTION & HANDLING		Pre-boning trim	51 A	Imports	81 A
Personal dress and habits	25 A	Boneless meat reinspection	52 A	HACCP	U
Personal hygiene practices	26 A	Ingredients identification	53 A		
Sanitary dressing procedures	27 A	Control of restricted ingredients	54 A	**COMMENTS MADE ON REVERSE**	

U.S. DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE
INTERNATIONAL PROGRAMS

FOREIGN PLANT REVIEW FORM

REVIEW DATE	ESTABLISHMENT NO. AND NAME	CITY
05/18/01	Est. 363-L Montorse Francesco e Figli S.P.A.	Villa Franca
		COUNTRY: ITALY

NAME OF REVIEWER	NAME OF FOREIGN OFFICIAL	EVALUATION
Dr. F. CHOUDRY & Dr. G. Mughal	Dr. Foroni, Supervisor & Dr. Residoni, IIC	☐ Acceptable ☒ Acceptable/ Re-review ☐ Unacceptable

CODES (Give an appropriate code for each review item listed below)
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1. CONTAMINATION CONTROL		Cross contamination prevention	28 A	Formulations	55 A
(a) BASIC ESTABLISHMENT FACILITIES		Equipment Sanitizing	29 A	Packaging materials	56 A
Water potability records	01 A	Product handling and storage	30 A	Laboratory confirmation	57 A
Chlorination procedures	02 O	Product reconditioning	31 A	Label approvals	58 A
Back siphonage prevention	03 A	Product transportation	32 A	Special label claims	59 O
Hand washing facilities	04 A	**(d) ESTABLISHMENT SANITATION PROGRAM**		Inspector monitoring	60 A
Sanitizers	05 A	Effective maintenance program	33 A	Processing schedules	61 A
Establishments separation	06 A	Preoperational sanitation	34 M	Processing equipment	62 A
Pest --no evidence	07 A	Operational sanitation	35 M	Processing records	63 A
Pest control program	08 A	Waste disposal	36 A	Empty can inspection	64 O
Pest control monitoring	09 A	**2. DISEASE CONTROL**		Filling procedures	65 O
Temperature control	10 A	Animal identification	37 O	Container closure exam	66 O
Lighting	11 A	Antemortem inspec. procedures	38 O	Interim container handling	67 O
Operations work space	12 A	Antemortem dispositions	39 O	Post-processing handling	68 O
Inspector work space	13 O	Humane Slaughter	40 O	Incubation procedures	69 O
Ventilation	14 A	Postmortem inspec. procedures	41 O	Process. defect actions -- plant	70 A
Facilities approval	15 A	Postmortem dispositions	42 O	Processing control -- inspection	71 A
Equipment approval	16 A	Condemned product control	43 A	**5. COMPLIANCE/ECON. FRAUD CONTROL**	
(b) CONDITION OF FACILITIES EQUIPMENT		Restricted product control	44 O	Export product identification	72 A
Over-product ceilings	17 U	Returned and rework product	45 A	Inspector verification	73 A
Over-product equipment	18 M	**3. RESIDUE CONTROL**		Export certificates	74 A
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Dry storage areas	21 A	Residue reporting procedures	48 O	Control of security items	77 A
Antemortem facilities	22 O	Approval of chemicals, etc.	49 A	Shipment security	78 A
Welfare facilities	23 A	Storage and use of chemicals	50 A	Species verification	79 O
Outside premises	24 A	**4. PROCESSED PRODUCT CONTROL**		"Equal to" status	80 A
(c) PRODUCT PROTECTION & HANDLING		Pre-boning trim	51 A	Imports	81 A
Personal dress and habits	25 A	Boneless meat reinspection	52 O	HACCP	U
Personal hygiene practices	26 A	Ingredients identification	53 A		
Sanitary dressing procedures	27 O	Control of restricted ingredients	54 A	**COMMENTS MADE ON REVERSE**	

U.S. DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE
INTERNATIONAL PROGRAMS

FOREIGN PLANT REVIEW FORM

REVIEW DATE	ESTABLISHMENT NO. AND NAME	CITY
5/17/01	Est.0500 L Carpegna Prosciutti S.P.A.	Carpegna
		COUNTRY Italy

NAME OF REVIEWER	NAME OF FOREIGN OFFICIAL	EVALUATION
M. Ghias Mughal, DVM	Dr. Magalotti	☐ Acceptable ☒ Acceptable/ Re-review ☐ Unacceptable

CODES (Give an appropriate code for each review item listed below)
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1. CONTAMINATION CONTROL		Cross contamination prevention	28 A	Formulations	55 A
(a) BASIC ESTABLISHMENT FACILITIES		Equipment Sanitizing	29 A	Packaging materials	56 A
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Chlorination procedures	02 A	Product reconditioning	31 U	Label approvals	58 A
Back siphonage prevention	03 A	Product transportation	32 A	Special label claims	59 A
Hand washing facilities	04 A	**(d) ESTABLISHMENT SANITATION PROGRAM**		Inspector monitoring	60 A
Sanitizers	05 A	Effective maintenance program	33 A	Processing schedules	61 A
Establishments separation	06 A	Preoperational sanitation	34 A	Processing equipment	62 A
Pest --no evidence	07 A	Operational sanitation	35 A	Processing records	63 A
Pest control program	08 A	Waste disposal	36 A	Empty can inspection	64 O
Pest control monitoring	09 A	**2. DISEASE CONTROL**		Filling procedures	65 O
Temperature control	10 A	Animal identification	37 O	Container closure exam	66 O
Lighting	11 A	Antemortem inspec. procedures	38 O	Interim container handling	67 O
Operations work space	12 A	Antemortem dispositions	39 O	Post-processing handling	68 O
Inspector work space	13 O	Humane Slaughter	40 O	Incubation procedures	69 O
Ventilation	14 A	Postmortem inspec. procedures	41 O	Process. defect actions -- plant	70 O
Facilities approval	15 A	Postmortem dispositions	42 O	Processing control -- inspection	71 A
Equipment approval	16 A	Condemned product control	43 U	**5. COMPLIANCE/ECON. FRAUD CONTROL**	
(b) CONDITION OF FACILITIES EQUIPMENT		Restricted product control	44 A	Export product identification	72 A
Over-product ceilings	17 A	Returned and rework product	45 N	Inspector verification	73 A
Over-product equipment	18 A	**3. RESIDUE CONTROL**		Export certificates	74 A
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Dry storage areas	21 U	Residue reporting procedures	48 A	Control of security items	77 A
Antemortem facilities	22 O	Approval of chemicals, etc.	49 A	Shipment security	78 A
Welfare facilities	23 A	Storage and use of chemicals	50 A	Species verification	79 A
Outside premises	24 A	**4. PROCESSED PRODUCT CONTROL**		"Equal to" status	80 A
(c) PRODUCT PROTECTION & HANDLING		Pre-boning trim	51 O	Imports	81 A
Personal dress and habits	25 A	Boneless meat reinspection	52 O		
Personal hygiene practices	26 A	Ingredients identification	53 A		
Sanitary dressing procedures	27 A	Control of restricted ingredients	54 A		

U.S. DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE
INTERNATIONAL PROGRAMS

FOREIGN PLANT REVIEW FORM

REVIEW DATE	ESTABLISHMENT NO. AND NAME	CITY
5/31/01	Est.0508 L Rovagnati S.p. A.	Biassono
		COUNTRY Italy

NAME OF REVIEWER	NAME OF FOREIGN OFFICIAL	EVALUATION
M. Ghias Mughal, DVM	Dr. D. D'Angelo	[X] Acceptable [ ] Acceptable/ Re-review [ ] Unacceptable

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Establishments separation	06 A	Preoperational sanitation	34 A	Processing equipment	62 A
Pest --no evidence	07 A	Operational sanitation	35 A	Processing records	63 A
Pest control program	08 A	Waste disposal	36 A	Empty can inspection	64 O
Pest control monitoring	09 A	**2. DISEASE CONTROL**		Filling procedures	65 O
Temperature control	10 A	Animal identification	37 O	Container closure exam	66 O
Lighting	11 A	Antemortem inspec. procedures	38 O	Interim container handling	67 O
Operations work space	12 A	Antemortem dispositions	39 O	Post-processing handling	68 O
Inspector work space	13 O	Humane Slaughter	40 O	Incubation procedures	69 O
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(c) PRODUCT PROTECTION & HANDLING		Pre-boning trim	51 O	Imports	81 A
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Personal hygiene practices	26 A	Ingredients identification	53 A		
Sanitary dressing procedures	27 A	Control of restricted ingredients	54 A		

U.S. DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE
INTERNATIONAL PROGRAMS

FOREIGN PLANT REVIEW FORM

REVIEW DATE	ESTABLISHMENT NO. AND NAME	CITY
5/25/01	Est. 0515 L Salumificio la Torre di Grassi	Langhirano
		COUNTRY Italy

NAME OF REVIEWER	NAME OF FOREIGN OFFICIAL	EVALUATION
M. Ghias Mughal, DVM	Dr. R. Ciati	[X] Acceptable [ ] Acceptable/ Re-review [ ] Unacceptable

CODES (Give an appropriate code for each review item listed below)
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Establishments separation	06 A	Preoperational sanitation	34 A	Processing equipment	62 A
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Pest control program	08 A	Waste disposal	36 A	Empty can inspection	64 O
Pest control monitoring	09 A	**2. DISEASE CONTROL**		Filling procedures	65 O
Temperature control	10 A	Animal identification	37 O	Container closure exam	66 O
Lighting	11 A	Antemortem inspec. procedures	38 O	Interim container handling	67 O
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Equipment approval	16 A	Condemned product control	43 U	**5. COMPLIANCE/ECON. FRAUD CONTROL**	
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Outside premises	24 A	**4. PROCESSED PRODUCT CONTROL**		"Equal to" status	80 A
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Personal hygiene practices	26 A	Ingredients identification	53 A		
Sanitary dressing procedures	27 A	Control of restricted ingredients	54 A		

U.S. DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE
INTERNATIONAL PROGRAMS

FOREIGN PLANT REVIEW FORM

REVIEW DATE	ESTABLISHMENT NO. AND NAME	CITY
05/28/0	Est. 550-L Casale S.P.A.	Felino (PR) COUNTRY ITALY

NAME OF REVIEWER	NAME OF FOREIGN OFFICIAL	EVALUATION
Dr. Faiz R. Choudry	Dr. Cozzolino, Supervisor	☐ Acceptable ☒ Acceptable/ Re-review ☐ Unacceptable

CODES (Give an appropriate code for each review item listed below)
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Pest control monitoring	09 A	**2. DISEASE CONTROL**		Filling procedures	65 O
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Ventilation	14 A	Postmortem inspec. procedures	41 O	Process. defect actions -- plant	70 O
Facilities approval	15 A	Postmortem dispositions	42 O	Processing control -- inspection	71 A
Equipment approval	16 A	Condemned product control	43 M	**5. COMPLIANCE/ECON. FRAUD CONTROL**	
(b) CONDITION OF FACILITIES EQUIPMENT		Restricted product control	44 A	Export product identification	72 A
Over-product ceilings	17 A	Returned and rework product	45 N	Inspector verification	73 A
Over-product equipment	18 M	**3. RESIDUE CONTROL**		Export certificates	74 A
Product contact equipment	19 A	Residue program compliance	46 O	Single standard	75 A
Other product areas *(inside)*	20 A	Sampling procedures	47 O	Inspection supervision	76 M
Dry storage areas	21 U	Residue reporting procedures	48 O	Control of security items	77 A
Antemortem facilities	22 O	Approval of chemicals, etc.	49 A	Shipment security	78 A
Welfare facilities	23 A	Storage and use of chemicals	50 A	Species verification	79 O
Outside premises	24 A	**4. PROCESSED PRODUCT CONTROL**		"Equal to" status	80 A
(c) PRODUCT PROTECTION & HANDLING		Pre-boning trim	51 A	Imports	81 O
Personal dress and habits	25 A	Boneless meat reinspection	52 O		
Personal hygiene practices	26 M	Ingredients identification	53 A		
Sanitary dressing procedures	27 O	Control of restricted ingredients	54 O	**COMMENTS MADE ON REVERSE**	

U.S. DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE
INTERNATIONAL PROGRAMS

FOREIGN PLANT REVIEW FORM

REVIEW DATE	ESTABLISHMENT NO. AND NAME	CITY
05/15/01	Est. 643 M/S F. LLi Martelli S.P.A.	Dosolo (MN) COUNTRY ITAL:Y

NAME OF REVIEWER	NAME OF FOREIGN OFFICIAL	EVALUATION
Dr. Faiz R. Choudry	Dr. Fucilli & Dr. Festa A. Cell, Supervisor	☐ Acceptable ☐ Acceptable/ Re-review ☒ Unacceptable

CODES (Give an appropriate code for each review item listed below)
A = Acceptable M = Marginally Acceptable U = Unacceptable N = Not Reviewed O = Does not apply

1. CONTAMINATION CONTROL		Cross contamination prevention	28 M	Formulations	55 O
(a) BASIC ESTABLISHMENT FACILITIES		Equipment Sanitizing	29 A	Packaging materials	56 A
Water potability records	01 A	Product handling and storage	30 A	Laboratory confirmation	57 O
Chlorination procedures	02 O	Product reconditioning	31 M	Label approvals	58 A
Back siphonage prevention	03 A	Product transportation	32 A	Special label claims	59 O
Hand washing facilities	04 A	(d) ESTABLISHMENT SANITATION PROGRAM		Inspector monitoring	60 O
Sanitizers	05 M	Effective maintenance program	33 A	Processing schedules	61 O
Establishments separation	06 A	Preoperational sanitation	34 M	Processing equipment	62 O
Pest --no evidence	07 A	Operational sanitation	35 M	Processing records	63 O
Pest control program	08 A	Waste disposal	36 A	Empty can inspection	64 O
Pest control monitoring	09 A	2. DISEASE CONTROL		Filling procedures	65 O
Temperature control	10 A	Animal identification	37 A	Container closure exam	66 O
Lighting	11 M	Antemortem inspec. procedures	38 A	Interim container handling	67 O
Operations work space	12 A	Antemortem dispositions	39 A	Post-processing handling	68 O
Inspector work space	13 A	Humane Slaughter	40 A	Incubation procedures	69 O
Ventilation	14 A	Postmortem inspec. procedures	41 A	Process. defect actions -- plant	70 O
Facilities approval	15 A	Postmortem dispositions	42 A	Processing control -- inspection	71 A
Equipment approval	16 A	Condemned product control	43 M	5. COMPLIANCE/ECON. FRAUD CONTROL	
(b) CONDITION OF FACILITIES EQUIPMENT		Restricted product control	44 A	Export product identification	72 A
Over-product ceilings	17 U	Returned and rework product	45 N	Inspector verification	73 A
Over-product equipment	18 M	3. RESIDUE CONTROL		Export certificates	74 A
Product contact equipment	19 M	Residue program compliance	46 A	Single standard	75 A
Other product areas *(inside)*	20 M	Sampling procedures	47 A	Inspection supervision	76 A
Dry storage areas	21 A	Residue reporting procedures	48 A	Control of security items	77 A
Antemortem facilities	22 A	Approval of chemicals, etc.	49 A	Shipment security	78 A
Welfare facilities	23 A	Storage and use of chemicals	50 A	Species verification	79 O
Outside premises	24 A	4. PROCESSED PRODUCT CONTROL		"Equal to" status	80 U
(c) PRODUCT PROTECTION & HANDLING		Pre-boning trim	51 A	Imports	81 O
Personal dress and habits	25 A	Boneless meat reinspection	52 O	HACCP	
Personal hygiene practices	26 M	Ingredients identification	53 O		
Sanitary dressing procedures	27 A	Control of restricted ingredients	54 O	COMMENTS MADE ON REVERSE	

U.S. DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE
INTERNATIONAL PROGRAMS

FOREIGN PLANT REVIEW FORM

REVIEW DATE	ESTABLISHMENT NO. AND NAME	CITY
5/23/01	Est.0648 L G. Bellentani 1821 S.P.A.	Vignola
		COUNTRY Italy

NAME OF REVIEWER	NAME OF FOREIGN OFFICIAL	EVALUATION
M. Ghias Mughal, DVM	Dr. A. Muzzioli	[X] Acceptable [ ] Acceptable/ Re-review [ ] Unacceptable

CODES (Give an appropriate code for each review item listed below)
A = Acceptable M = Marginally Acceptable U = Unacceptable N = Not Reviewed O = Does not apply

1. CONTAMINATION CONTROL							
(a) BASIC ESTABLISHMENT FACILITIES		Cross contamination prevention	28 A	Formulations	55 A
		Equipment Sanitizing	29 A	Packaging materials	56 A
Water potability records	01 A	Product handling and storage	30 A	Laboratory confirmation	57 A
Chlorination procedures	02 A	Product reconditioning	31 A	Label approvals	58 A
Back siphonage prevention	03 A	Product transportation	32 A	Special label claims	59 A
Hand washing facilities	04 A	(d) ESTABLISHMENT SANITATION PROGRAM		Inspector monitoring	60 A
Sanitizers	05 A	Effective maintenance program	33 A	Processing schedules	61 A
Establishments separation	06 A	Preoperational sanitation	34 A	Processing equipment	62 A
Pest --no evidence	07 A	Operational sanitation	35 A	Processing records	63 A
Pest control program	08 A	Waste disposal	36 A	Empty can inspection	64 O
Pest control monitoring	09 A	2. DISEASE CONTROL		Filling procedures	65 O
Temperature control	10 A	Animal identification	37 O	Container closure exam	66 O
Lighting	11 A	Antemortem inspec. procedures	38 O	Interim container handling	67 O
Operations work space	12 A	Antemortem dispositions	39 O	Post-processing handling	68 O
Inspector work space	13 O	Humane Slaughter	40 O	Incubation procedures	69 O
Ventilation	14 A	Postmortem inspec. procedures	41 O	Process. defect actions -- plant	70 O
Facilities approval	15 A	Postmortem dispositions	42 O	Processing control -- inspection	71 A
Equipment approval	16 A	Condemned product control	43 A	5. COMPLIANCE/ECON. FRAUD CONTROL	
(b) CONDITION OF FACILITIES EQUIPMENT		Restricted product control	44 A	Export product identification	72 A
Over-product ceilings	17 M	Returned and rework product	45 N	Inspector verification	73 A
Over-product equipment	18 M	3. RESIDUE CONTROL		Export certificates	74 A
Product contact equipment	19 M	Residue program compliance	46 A	Single standard	75 A
Other product areas *(inside)*	20 M	Sampling procedures	47 A	Inspection supervision	76 A
Dry storage areas	21 A	Residue reporting procedures	48 A	Control of security items	77 A
Antemortem facilities	22 O	Approval of chemicals, etc.	49 A	Shipment security	78 A
Welfare facilities	23 A	Storage and use of chemicals	50 A	Species verification	79 A
Outside premises	24 A	4. PROCESSED PRODUCT CONTROL		"Equal to" status	80 A
(c) PRODUCT PROTECTION & HANDLING		Pre-boning trim	51 O	Imports	81 A
Personal dress and habits	25 A	Boneless meat reinspection	52 O		
Personal hygiene practices	26 A	Ingredients identification	53 A		
Sanitary dressing procedures.	27 A	Control of restricted ingredients	54 A		

U.S. DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE
INTERNATIONAL PROGRAMS

FOREIGN PLANT REVIEW FORM

REVIEW DATE	ESTABLISHMENT NO. AND NAME	CITY
05/30/01	Est. 768 Industrie Riunite Campagnolo S. P. A.	Candiolo (TO) COUNTRY ITALY

NAME OF REVIEWER	NAME OF FOREIGN OFFICIAL	EVALUATION
Dr. F. Choudry & Ms. Sally Statmoen	Dr. Alberto Mancuso & Dr. Griglio Bartolomio	☐ Acceptable ☐ Acceptable/ Re-review ☒ Unacceptable

CODES (Give an appropriate code for each review item listed below)
A = Acceptable M = Marginally Acceptable U = Unacceptable N = Not Reviewed O = Does not apply

1. CONTAMINATION CONTROL		Cross contamination prevention	28 U	Formulations	55 O
(a) BASIC ESTABLISHMENT FACILITIES		Equipment Sanitizing	29 A	Packaging materials	56 A
Water potability records	01 A	Product handling and storage	30 A	Laboratory confirmation	57 O
Chlorination procedures	02 O	Product reconditioning	31 A	Label approvals	58 A
Back siphonage prevention	03 A	Product transportation	32 A	Special label claims	59 O
Hand washing facilities	04 A	(d) ESTABLISHMENT SANITATION PROGRAM		Inspector monitoring	60 A
Sanitizers	05 U	Effective maintenance program	33 A	Processing schedules	61 O
Establishments separation	06 A	Preoperational sanitation	34 U	Processing equipment	62 O
Pest --no evidence	07 M	Operational sanitation	35 U	Processing records	63 O
Pest control program	08 A	Waste disposal	36 A	Empty can inspection	64 O
Pest control monitoring	09 A	2. DISEASE CONTROL		Filling procedures	65 O
Temperature control	10 A	Animal identification	37 A	Container closure exam	66 O
Lighting	11 A	Antemortem inspec. procedures	38 A	Interim container handling	67 O
Operations work space	12 A	Antemortem dispositions	39 A	Post-processing handling	68 O
Inspector work space	13 A	Humane Slaughter	40 A	Incubation procedures	69 O
Ventilation	14 A	Postmortem inspec. procedures	41 U	Process. defect actions -- plant	70 O
Facilities approval	15 A	Postmortem dispositions	42 A	Processing control -- inspection	71 A
Equipment approval	16 A	Condemned product control	43 A	5. COMPLIANCE/ECON. FRAUD CONTROL	
(b) CONDITION OF FACILITIES EQUIPMENT		Restricted product control	44 A	Export product identification	72 A
Over-product ceilings	17 U	Returned and rework product	45 N	Inspector verification	73 A
Over-product equipment	18 M	3. RESIDUE CONTROL		Export certificates	74 A
Product contact equipment	19 U	Residue program compliance	46 A	Single standard	75 A
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Dry storage areas	21 M	Residue reporting procedures	48 A	Control of security items	77 A
Antemortem facilities	22 A	Approval of chemicals, etc.	49 A	Shipment security	78 A
Welfare facilities	23 A	Storage and use of chemicals	50 A	Species verification	79 O
Outside premises	24 A	4. PROCESSED PRODUCT CONTROL		"Equal to" status	80 U
(c) PRODUCT PROTECTION & HANDLING		Pre-boning trim	51 A	Imports	81 O
Personal dress and habits	25 A	Boneless meat reinspection	52 O	HACCP	U
Personal hygiene practices	26 U	Ingredients identification	53 O		
Sanitary dressing procedures	27 A	Control of restricted ingredients	54 O	COMMENTS MADE ON REVERSE	

U.S. DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE
INTERNATIONAL PROGRAMS

FOREIGN PLANT REVIEW FORM

REVIEW DATE	ESTABLISHMENT NO. AND NAME	CITY
05/25/01	Est. 791 M/S Italcarni Soc. Coop. A.R.L.	Migliarina Di Carpi
		COUNTRY ITALY

NAME OF REVIEWER	NAME OF FOREIGN OFFICIAL	EVALUATION
Dr. Faiz R. Choudry	Dr. Pierantoni; Dr. Noe; & Dr. Emore Vezzani	☐ Acceptable ☒ Acceptable/ Re-review ☐ Unacceptable

CODES (Give an appropriate code for each review item listed below)
A = Acceptable M = Marginally Acceptable U = Unacceptable N = Not Reviewed O = Does not apply

1. CONTAMINATION CONTROL		Cross contamination prevention	28 A	Formulations	55 A
(a) BASIC ESTABLISHMENT FACILITIES		Equipment Sanitizing	29 A	Packaging materials	56 A
Water potability records	01 A	Product handling and storage	30 A	Laboratory confirmation	57 A
Chlorination procedures	02 O	Product reconditioning	31 A	Label approvals	58 A
Back siphonage prevention	03 A	Product transportation	32 A	Special label claims	59 A
Hand washing facilities	04 A	**(d) ESTABLISHMENT SANITATION PROGRAM**		Inspector monitoring	60 A
Sanitizers	05 A	Effective maintenance program	33 A	Processing schedules	61 A
Establishments separation	06 A	Preoperational sanitation	34 A	Processing equipment	62 A
Pest --no evidence	07 A	Operational sanitation	35 A	Processing records	63 A
Pest control program	08 A	Waste disposal	36 A	Empty can inspection	64 A
Pest control monitoring	09 A	**2. DISEASE CONTROL**		Filling procedures	65 A
Temperature control	10 A	Animal identification	37 A	Container closure exam	66 A
Lighting	11 A	Antemortem inspec. procedures	38 A	Interim container handling	67 A
Operations work space	12 A	Antemortem dispositions	39 A	Post-processing handling	68 A
Inspector work space	13 A	Humane Slaughter	40 A	Incubation procedures	69 A
Ventilation	14 A	Postmortem inspec. procedures	41 A	Process. defect actions -- plant	70 A
Facilities approval	15 A	Postmortem dispositions	42 A	Processing control -- inspection	71 A
Equipment approval	16 A	Condemned product control	43 M	**5. COMPLIANCE/ECON. FRAUD CONTROL**	
(b) CONDITION OF FACILITIES EQUIPMENT		Restricted product control	44 A	Export product identification	72 A
Over-product ceilings	17 U	Returned and rework product	45 A	Inspector verification	73 A
Over-product equipment	18 A	**3. RESIDUE CONTROL**		Export certificates	74 A
Product contact equipment	19 M	Residue program compliance	46 A	Single standard	75 A
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Dry storage areas	21 A	Residue reporting procedures	48 A	Control of security items	77 A
Antemortem facilities	22 A	Approval of chemicals, etc.	49 A	Shipment security	78 A
Welfare facilities	23 A	Storage and use of chemicals	50 A	Species verification	79 A
Outside premises	24 A	**4. PROCESSED PRODUCT CONTROL**		"Equal to" status	80 A
(c) PRODUCT PROTECTION & HANDLING		Pre-boning trim	51 A	Imports	81 A
Personal dress and habits	25 A	Boneless meat reinspection	52 A		
Personal hygiene practices	26 A	Ingredients identification	53 A		
Sanitary dressing procedures	27 A	Control of restricted ingredients	54 A	**COMMENTS MADE ON REVERSE**	

U.S. DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE
INTERNATIONAL PROGRAMS

FOREIGN PLANT REVIEW FORM

REVIEW DATE	ESTABLISHMENT NO. AND NAME	CITY
5/16/01	Est. 0972 L Industrie Salumi Simonini	Faenza
		COUNTRY: Italy

NAME OF REVIEWER	NAME OF FOREIGN OFFICIAL	EVALUATION
M. Ghias Mughal, DVM	Dr. Bandini	[X] Acceptable [ ] Acceptable/ Re-review [ ] Unacceptable

CODES (Give an appropriate code for each review item listed below)
A = Acceptable M = Marginally Acceptable U = Unacceptable N = Not Reviewed O = Does not apply

1. CONTAMINATION CONTROL		Cross contamination prevention	28 A	Formulations	55 A
(a) BASIC ESTABLISHMENT FACILITIES		Equipment Sanitizing	29 A	Packaging materials	56 A
Water potability records	01 A	Product handling and storage	30 A	Laboratory confirmation	57 A
Chlorination procedures	02 A	Product reconditioning	31 A	Label approvals	58 A
Back siphonage prevention	03 A	Product transportation	32 A	Special label claims	59 A
Hand washing facilities	04 A	**(d) ESTABLISHMENT SANITATION PROGRAM**		Inspector monitoring	60 A
Sanitizers	05 A	Effective maintenance program	33 A	Processing schedules	61 A
Establishments separation	06 A	Preoperational sanitation	34 A	Processing equipment	62 A
Pest --no evidence	07 U	Operational sanitation	35 A	Processing records	63 A
Pest control program	08 A	Waste disposal	36 A	Empty can inspection	64 O
Pest control monitoring	09 A	**2. DISEASE CONTROL**		Filling procedures	65 O
Temperature control	10 A	Animal identification	37 O	Container closure exam	66 O
Lighting	11 A	Antemortem inspec. procedures	38 O	Interim container handling	67 O
Operations work space	12 A	Antemortem dispositions	39 O	Post-processing handling	68 O
Inspector work space	13 O	Humane Slaughter	40 O	Incubation procedures	69 O
Ventilation	14 A	Postmortem inspec. procedures	41 O	Process. defect actions -- plant	70 O
Facilities approval	15 A	Postmortem dispositions	42 O	Processing control -- inspection	71 A
Equipment approval	16 A	Condemned product control	43 U	**5. COMPLIANCE/ECON. FRAUD CONTROL**	
(b) CONDITION OF FACILITIES EQUIPMENT		Restricted product control	44 A	Export product identification	72 A
Over-product ceilings	17 A	Returned and rework product	45 N	Inspector verification	73 A
Over-product equipment	18 U	**3. RESIDUE CONTROL**		Export certificates	74 A
Product contact equipment	19 A	Residue program compliance	46 A	Single standard	75 A
Other product areas *(inside)*	20 U	Sampling procedures	47 A	Inspection supervision	76 A
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Antemortem facilities	22 O	Approval of chemicals, etc.	49 A	Shipment security	78 A
Welfare facilities	23 A	Storage and use of chemicals	50 A	Species verification	79 A
Outside premises	24 A	**4. PROCESSED PRODUCT CONTROL**		"Equal to" status	80 A
(c) PRODUCT PROTECTION & HANDLING		Pre-boning trim	51 O	Imports	81 A
Personal dress and habits	25 A	Boneless meat reinspection	52 O		
Personal hygiene practices	26 A	Ingredients identification	53 A		
Sanitary dressing procedures	27 A	Control of restricted ingredients	54 A		

U.S. DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE
INTERNATIONAL PROGRAMS

FOREIGN PLANT REVIEW FORM

REVIEW DATE	ESTABLISHMENT NO. AND NAME	CITY
05/11/01	Est. 989-L Corte Buona S.P. A.	Paliano (PR) COUNTRY: ITALY

NAME OF REVIEWER	NAME OF FOREIGN OFFICIAL	EVALUATION
Dr. F. Choudry & Dr. G. Mughal	Dr. Maestripieri IIC & Dr. DI-Fazio	☐ Acceptable ☐ Acceptable/ Re-review ☒ Unacceptable

CODES (Give an appropriate code for each review item listed below)
A = Acceptable M = Marginally Acceptable U = Unacceptable N = Not Reviewed O = Does not apply

1. CONTAMINATION CONTROL		Cross contamination prevention	28 M	Formulations	55 A
(a) BASIC ESTABLISHMENT FACILITIES		Equipment Sanitizing	29 A	Packaging materials	56 A
Water potability records	01 A	Product handling and storage	30 A	Laboratory confirmation	57 O
Chlorination procedures	02 O	Product reconditioning	31 A	Label approvals	58 A
Back siphonage prevention	03 A	Product transportation	32 A	Special label claims	59 O
Hand washing facilities	04 A	**(d) ESTABLISHMENT SANITATION PROGRAM**		Inspector monitoring	60 A
Sanitizers	05 U	Effective maintenance program	33 A	Processing schedules	61 A
Establishments separation	06 A	Preoperational sanitation	34 U	Processing equipment	62 A
Pest --no evidence	07 A	Operational sanitation	35 U	Processing records	63 A
Pest control program	08 M	Waste disposal	36 A	Empty can inspection	64 O
Pest control monitoring	09 A	**2. DISEASE CONTROL**		Filling procedures	65 O
Temperature control	10 A	Animal identification	37 O	Container closure exam	66 O
Lighting	11 A	Antemortem inspec. procedures	38 O	Interim container handling	67 O
Operations work space	12 A	Antemortem dispositions	39 O	Post-processing handling	68 O
Inspector work space	13 A	Humane Slaughter	40 O	Incubation procedures	69 O
Ventilation	14 A	Postmortem inspec. procedures	41 O	Process. defect actions -- plant	70 O
Facilities approval	15 A	Postmortem dispositions	42 O	Processing control -- inspection	71 A
Equipment approval	16 A	Condemned product control	43 A	**5. COMPLIANCE/ECON. FRAUD CONTROL**	
(b) CONDITION OF FACILITIES EQUIPMENT		Restricted product control	44 O	Export product identification	72 A
Over-product ceilings	17 U	Returned and rework product	45 N	Inspector verification	73 A
Over-product equipment	18 M	**3. RESIDUE CONTROL**		Export certificates	74 A
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Antemortem facilities	22 A	Approval of chemicals, etc.	49 A	Shipment security	78 A
Welfare facilities	23 A	Storage and use of chemicals	50 A	Species verification	79 O
Outside premises	24 A	**4. PROCESSED PRODUCT CONTROL**		"Equal to" status	80 U
(c) PRODUCT PROTECTION & HANDLING		Pre-boning trim	51 A	Imports	81 A
Personal dress and habits	25 A	Boneless meat reinspection	52 O	HACCP	U
Personal hygiene practices	26 A	Ingredients identification	53 A		
Sanitary dressing procedures	27 O	Control of restricted ingredients	54 A	COMMENTS MADE ON REVERSE	

U.S. DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE
INTERNATIONAL PROGRAMS

FOREIGN PLANT REVIEW FORM

REVIEW DATE	ESTABLISHMENT NO. AND NAME	CITY
5/29/01	Est. 1157/L Giuseppe Citterio Salumificio S.p. A.	Sala Baganza
		COUNTRY Italy

NAME OF REVIEWER	NAME OF FOREIGN OFFICIAL	EVALUATION
M. Ghias Mughal, DVM	Dr. A. Paratico	[X] Acceptable [ ] Acceptable/ Re-review [ ] Unacceptable

CODES (Give an appropriate code for each review item listed below)
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1. CONTAMINATION CONTROL		Cross contamination prevention	28 A	Formulations	55 A
(a) BASIC ESTABLISHMENT FACILITIES		Equipment Sanitizing	29 A	Packaging materials	56 A
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Pest control monitoring	09 A	**2. DISEASE CONTROL**		Filling procedures	65 O
Temperature control	10 A	Animal identification	37 O	Container closure exam	66 O
Lighting	11 A	Antemortem inspec. procedures	38 O	Interim container handling	67 O
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Inspector work space	13 O	Humane Slaughter	40 O	Incubation procedures	69 O
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Equipment approval	16 A	Condemned product control	43 U	**5. COMPLIANCE/ECON. FRAUD CONTROL**	
(b) CONDITION OF FACILITIES EQUIPMENT		Restricted product control	44 A	Export product identification	72 A
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Over-product equipment	18 A	**3. RESIDUE CONTROL**		Export certificates	74 A
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Welfare facilities	23 A	Storage and use of chemicals	50 A	Species verification	79 A
Outside premises	24 A	**4. PROCESSED PRODUCT CONTROL**		"Equal to" status	80 A
(c) PRODUCT PROTECTION & HANDLING		Pre-boning trim	51 O	Imports	81 A
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Personal hygiene practices	26 A	Ingredients identification	53 A		
Sanitary dressing procedures	27 A	Control of restricted ingredients	54 A		

U.S. DEPARTMENT OF AGRICULTURE FOOD SAFETY AND INSPECTION SERVICE INTERNATIONAL PROGRAMS **FOREIGN PLANT REVIEW FORM**	REVIEW DATE 5/24/01	ESTABLISHMENT NO. AND NAME Est. 1594/L Industria Macellazione Valle Del Leo S.p.A.	CITY Fanano COUNTRY Italy

NAME OF REVIEWER	NAME OF FOREIGN OFFICIAL	EVALUATION
M. Ghias Mughal, DVM	Dr.M. Chichi	[X] Acceptable [ ] Acceptable/ Re-review [ ] Unacceptable

CODES (Give an appropriate code for each review item listed below)
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1. CONTAMINATION CONTROL		Cross contamination prevention	28 A	Formulations	55 A
(a) BASIC ESTABLISHMENT FACILITIES		Equipment Sanitizing	29 A	Packaging materials	56 A
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Pest control monitoring	09 A	2. DISEASE CONTROL		Filling procedures	65 O
Temperature control	10 A	Animal identification	37 O	Container closure exam	66 O
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Inspector work space	13 O	Humane Slaughter	40 O	Incubation procedures	69 O
Ventilation	14 A	Postmortem inspec. procedures	41 O	Process. defect actions -- plant	70 O
Facilities approval	15 A	Postmortem dispositions	42 O	Processing control -- inspection	71 A
Equipment approval	16 A	Condemned product control	43 U	5. COMPLIANCE/ECON. FRAUD CONTROL	
(b) CONDITION OF FACILITIES EQUIPMENT		Restricted product control	44 A	Export product identification	72 A
Over-product ceilings	17 A	Returned and rework product	45 N	Inspector verification	73 A
Over-product equipment	18 A	3. RESIDUE CONTROL		Export certificates	74 A
Product contact equipment	19 A	Residue program compliance	46 A	Single standard	75 A
Other product areas *(inside)*	20 A	Sampling procedures	47 A	Inspection supervision	76 A
Dry storage areas	21 A	Residue reporting procedures	48 A	Control of security items	77 A
Antemortem facilities	22 O	Approval of chemicals, etc.	49 A	Shipment security	78 A
Welfare facilities	23 A	Storage and use of chemicals	50 A	Species verification	79 A
Outside premises	24 A	4. PROCESSED PRODUCT CONTROL		"Equal to" status	80 A
(c) PRODUCT PROTECTION & HANDLING		Pre-boning trim	51 O	Imports	81 A
Personal dress and habits	25 A	Boneless meat reinspection	52 O	HACCP- verification	M
Personal hygiene practices	26 A	Ingredients identification	53 A		
Sanitary dressing procedures	27 A	Control of restricted ingredients	54 A		

U.S. DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE
INTERNATIONAL PROGRAMS

FOREIGN PLANT REVIEW FORM

REVIEW DATE	ESTABLISHMENT NO. AND NAME	CITY
5/15/01	Est. 1597/L Ancona Carni S.r.L.	Ancona
		COUNTRY Italy

NAME OF REVIEWER	NAME OF FOREIGN OFFICIAL	EVALUATION
M. Ghias Mughal, DVM	Dr. P. Chicchirizini	☐ Acceptable ☐ Acceptable/ Re-review ☒ Unacceptable

CODES (Give an appropriate code for each review item listed below)
A = Acceptable M = Marginally Acceptable U = Unacceptable N = Not Reviewed O = Does not apply

1. CONTAMINATION CONTROL		Cross contamination prevention	28 A	Formulations	55 A
(a) BASIC ESTABLISHMENT FACILITIES		Equipment Sanitizing	29 A	Packaging materials	56 A
Water potability records	01 A	Product handling and storage	30 A	Laboratory confirmation	57 A
Chlorination procedures	02 A	Product reconditioning	31 A	Label approvals	58 U
Back siphonage prevention	03 A	Product transportation	32 A	Special label claims	59 A
Hand washing facilities	04 A	**(d) ESTABLISHMENT SANITATION PROGRAM**		Inspector monitoring	60 A
Sanitizers	05 U	Effective maintenance program	33 A	Processing schedules	61 A
Establishments separation	06 A	Preoperational sanitation	34 A	Processing equipment	62 A
Pest --no evidence	07 A	Operational sanitation	35 A	Processing records	63 A
Pest control program	08 A	Waste disposal	36 A	Empty can inspection	64 O
Pest control monitoring	09 A	**2. DISEASE CONTROL**		Filling procedures	65 O
Temperature control	10 A	Animal identification	37 O	Container closure exam	66 O
Lighting	11 A	Antemortem inspec. procedures	38 O	Interim container handling	67 O
Operations work space	12 A	Antemortem dispositions	39 O	Post-processing handling	68 O
Inspector work space	13 O	Humane Slaughter	40 O	Incubation procedures	69 O
Ventilation	14 A	Postmortem inspec. procedures	41 O	Process. defect actions -- plant	70 O
Facilities approval	15 A	Postmortem dispositions	42 O	Processing control -- inspection	71 A
Equipment approval	16 A	Condemned product control	43 U	**5. COMPLIANCE/ECON. FRAUD CONTROL**	
(b) CONDITION OF FACILITIES EQUIPMENT		Restricted product control	44 A	Export product identification	72 A
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Welfare facilities	23 A	Storage and use of chemicals	50 A	Species verification	79 A
Outside premises	24 A	**4. PROCESSED PRODUCT CONTROL**		"Equal to" status	80 U
(c) PRODUCT PROTECTION & HANDLING		Pre-boning trim	51 O	Imports	81 A
Personal dress and habits	25 A	Boneless meat reinspection	52 O	HACCP...See Attacment C	U
Personal hygiene practices	26 A	Ingredients identification	53 A		
Sanitary dressing procedures	27 A	Control of restricted ingredients	54 A		

U.S. DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE
INTERNATIONAL PROGRAMS

FOREIGN PLANT REVIEW FORM

REVIEW DATE: 5/24/01

ESTABLISHMENT NO. AND NAME: Est.1664 M/S Industria Macellazione Valle Del Leo S.P.A.

CITY: Fanano

COUNTRY: Italy

NAME OF REVIEWER: M. Ghias Mughal, DVM

NAME OF FOREIGN OFFICIAL: Dr. M. Chichi

EVALUATION: ☐ Acceptable ☐ Acceptable/ Re-review ☒ Unacceptable

CODES (Give an appropriate code for each review item listed below)
A = Acceptable M = Marginally Acceptable U = Unacceptable N = Not Reviewed O = Does not apply

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Personal hygiene practices	26 A	Ingredients identification	53 A		
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Attachment G

Ministero della Salute

DIREZIONE GENERALE DELLA SANITA PUBBLICA VETERINARIA , DEGLI ALIMENTI E DELLA NUTRIZIONE - UFF.III - VIII

John C. Prucha, D.V.M., M.S.,M.P.H.
Assistant Deputy Administrator
Food Inspection Service
USDA
Washington D.C.
20250

600.3/SP31/5967

6 OTT. 2001

SUBJECT: on-site audit of Italy's meat inspection program (May 7, 2001 – June 6, 2001).

Reference is made to your letter of 20 July 2001, delivered to us by hand on 2 August 2001 relating to the draft report on the audit of Italy's meat inspection system conducted from May 7, 2001, through June 6, 2001.

The opinion reported as " summary", according to which " the audit marks ...a three-year trend of gradually deteriorating conditions in many meat establishments that the Government of Italy has certified for export to United States, in particular establishments that slaughter swine " is in our view a bit too severe and is maybe based on the approach of the inspector responsible for the audits carried out in 2000 and 2001, which has been in some cases maximalist, as it will be better clarified in the annex.

Another critical point of the report is the stress put on the " inadequate central and regional supervision of local government inspection activities in Italian meat establishments ", which appears to be also supported by the inspections carried out in October and November 2000 by the EU Commission Food Veterinary Office. In this regard, it should be noted that remarks on the lack of supervision by the central and regional authorities on the activities carried out by the local authorities – which undoubtedly have to be taken seriously – are quite frequent in the reports of the Food Veterinary Office on EU Member States, and represent a stimulus for the competent

authorities to improve their control activities. In fact, when the FVO finds situations which may actually represent a hazard to EU consumer's health, more incisive measures on Member States are taken (for instance, request to suspend the operations of one or more establishments, starting up of an infringement procedure vis-à-vis the Member State concerned and so on). Therefore, the sentence according to which " the conclusion we reach from our last three audits – combined with correlation findings by the European Commission – is that Italy is on the brink of a meat inspection system failure " seems to us emphatic to say the least and not matching the actual situation.

This said, it has to be clarified that the draft report in question was a sort of shock for the meat production industry and for the control authorities. That is why over the last few months certain measures were taken to further improve the situation. In particular:

- A working group composed of veterinary staff from the Ministry of Health and from the Regions was created in order to rationalize the inspection and control procedures by 1) drawing up uniform operative procedures 2) drawing up forms to record the checks carried out respectively by the official veterinarians and by the head of the veterinary service and 3) drawing up specimen report forms for the inspections carried out by the regional and ministerial inspectors;
- In the 17 September– 5 October 2001 period training courses on the US regulations were organized for the veterinarians and operators working into the establishments approved for export to the United States;
- The Regional authorities, by means of the Veterinary services of the Local Health Units, are currently supervising all the establishments included on the list of establishments approved for export to the United States located on their relevant territories, and a particular stress was put on the proper implementation of SSOPs and HACCP.
- In September 2001 the veterinary staff of the Ministry of Health has been increased, thus enabling us to assign more staff to inspection activities.

We look forward to receiving news from you concerning the new inspection that will seemingly take place at the end of this year.

Best regards.

The Director General
(Dr Romano Marabelli)

cc

Alejandro Checchi-Lang
European Commission

MEASURES ADOPTED AND REMARKS

1. Audit on the inspection system

SUPERVISION BY GOVERNMENT AUTHORITIES

With reference to the findings of the FSIS-USDA inspection of May – June 2001, and following the remarks already reported in our letter 600.3/SP31/3834 of 5 June 2001 in reply to the report on the previous inspection carried out in September 2000, we would like to supply the pieces of information below.

On the basis of the remarks contained in the September 2000 inspection report, by letter ref. 600.3.8/80.83/AG/262 of 26 April 2001 the Ministry of Health gave the Regional authorities and the Local Health Units instructions on the need to implement the following procedures in the own-check plan of establishments:
- SSOPs divided into pre-operational and operational,
- GMPs,
- HACCP program containing: a) hazard identification; b) identification of critical points; c) control of critical points; d) establishment of acceptability levels; e) monitoring of critical control points; f) adoption of corrective and preventive measures; g) data recording; h) validation of the procedure; i) pre-shipment review.

Moreover, the above mentioned letter also recalled the instructions already supplied on E. Coli testing program and on the application of Salmonella testing.

Moreover, the tasks of the official veterinarian responsible for the establishment were made clear in connection with the veterinary supervision of the establishment's own-check plan and the official control; moreover, we reiterated the need for a monthly supervision to be carried out by the head of the veterinary service or by a person delegated by him on the activities performed by the official veterinarian, as well as and for a regional supervision on the local veterinary service.

As already communicated to the inspectors during the final meeting, a stricter procedure for including establishments on the US list was established.

In fact, before being included on the lists for export to the United States, the establishments must implement all the procedures and operate according to the provisions on own-checks (GMP,SSOP-HACCP) beginning from their application for registration and for a period not lower than three months.

At the end of this period the Local Health Unit shall send the Ministry of Health a copy of the validation of these procedures, undersigned by the person who drew them up, together with the favorable opinion issued by the Veterinary Service. Before including the establishment on the list, an inspection has to be carried out by inspectors from the Ministry of Health.

In September 2001 the veterinary staff of the Ministry of Health was increased, thus enabling us to devote more staff to inspection activities.

The list of establishments approved for export to the United States is drawn up by the Ministry of Health, which is in charge of submitting the registration proposal to the US authorities and of possibly delisting establishments..

For those establishments already included on the list we requested the Local Health Units to send us a report on the implementation of own-check procedures and the operation data, in particular regarding the products exported to the US over the last two years, in order to remain on the list in question.

As far as slaughterhouses included on the US list an inspection by this Ministry will be carried out as soon as possible.

Within their own inspection programs, the Regional authorities were invited to increase the inspections activities on the establishments approved for export to the United States.

The recently-hired veterinary staff at the Ministry of Health will allow a planning of ministerial audits on the Regions and more verification inspections on the establishments.

With reference to the findings of the FSIS-USDA inspection in May-June 2001 a working group composed of veterinary staff from the Ministry of Health and from the Regions was created, in order to rationalize the inspection and control by 1) drawing up uniform operative procedures 2) drawing up forms to record the checks carried out respectively by the official veterinarians and by the head of the veterinary service and 3) drawing up specimen report forms for inspections carried out by the regional and ministerial inspectors.

In particular, the above mentioned working group will address:

- Forms (drawing up of check-list and other forms),
- Intervals of checks,
- Operative procedures,
- Procedures for solving non-compliance,
- Methods for recording files.

With reference to zero tolerance the working group will underline the responsibility of companies in establishing the critical control point in order to monitor fecal contamination of the carcasses.

With respect to the verification of own-check procedures the above mentioned working group will draw up appropriate guidelines based on the draft circular letter already submitted to the Regional authorities by the Ministry of Health in October 2000 and in compliance with the obligations laid down by Decision 2001/471/EC, which foresees the implementation and maintenance of a permanent own-check procedure in slaughterhouses according to the HACCP principles.

These guidelines will concern;

- Prerequisites

- HACCP principles
- Operative instructions for assessment.

SUPERVISION BY THE REGIONAL AND LOCAL AUTHORITIES

The Regional veterinary services carry out inspection activities both for assigning establishments the EU approval and for supervising already approved establishments.

The permanent veterinary supervision on establishments approved for exports to the United States, as well as on all EU-approved establishments, is the task of the Veterinary Services of the Local Health Units.

According to the local situation and to the distribution of production in the various Regions, the regional supervision is organized on the basis of criteria which may seem uneven.

For instance, the operative veterinary unit of the Lombardia Region draws up and implements an annual planning of inspections aimed at verifying that the activities of the Veterinary Services of the Local Health Units are performed properly.

Moreover, the Regional authorities carry out inspections on establishments in the event that the Veterinary Service of the Local Health Unit or any other control body finds particularly serious problems.

In all these cases the regional inspector must draw up an inspection report, remark non-conformities and prescribe the corrective measures to be implemented.

Where serious deficiencies are found, the Regional authority must suspend or withdraw the EU approval of the establishment, and this necessarily entails also the suspension or withdrawal of the approval for export to Third Countries.

Within their guidance and co-ordination tasks for the Veterinary services of the Local Health Units, some Regions issued their own guidelines for permanent veterinary supervision in order to assure a better and more even level of control activities by these very Services on the whole regional territory.

As far as training and refresher courses for veterinary inspectors are concerned, some Regions organized training activities; for instance, in the 1999-2000 period the Lombardia Region carried out a course on the assessment of own-check programs of food businesses, which involved veterinary inspectors coming from all the Local Health Units in the Region; moreover, this same Region planned a training course aimed at creating an inspection group to support the officers from the regional veterinary operative unit in supervising establishments already approved or to be approved.

Following the audit of the FSIS inspectors in May-June 2001, certain Regional authorities held meetings with representatives of the Veterinary Services of all the LHUs located on their territories in order to illustrate the inspection findings; these meetings were an opportunity to recall the requirements necessary to include

establishments on the list of food businesses approved for export to the United States and to stress the importance of a more continuous supervision by the Veterinary Services.

In application of the requests of the Ministry of Health, the Regional authorities, by means of the LHU Veterinary Services, are carrying out a verification of all the establishments included on the list for export to the United States located on their respective territories, with a particular stress on the proper implementation of SSOP and HACCP procedures.

The Regions also carried out random inspections on some establishments among those included on the US list by means of their own veterinary inspection staff.

REMARKS ON THE 2001 FSIS USDA REPORT

With reference to the remarks made in the USDA/FSIS inspection report of the May-2001 audit, we would like to make the comments below; nevertheless, it should be noted that in our view the importance that the single inspectors attributed to each of the deficiencies found appears to have changed in comparison with the previous audits.

The findings of the audits carried out over the last three years

The table below illustrates the findings of the inspections performed in slaughterhouses, and refer to the US audits performed in 1999, 2000 and 2001. First of all, it should be noted that not less than 7 establishments out of 9 were delisted (one of these was subsequently re-listed). Moreover, it should be noted that during the audits carried out this year not even an establishments has been considered as "acceptable".

Slaughterhouses	*1999*	*2000*	*2001*
Audited	8	7	8
Acceptable	4	3	0
Marginal	4	2	3
Unacceptable	0	2	5

The results of the audits on establishments manufacturing meat products were not as dreadful (see table below). This can be only partly explained by the different type of production, since the deficiencies in the SSOP and HACCP procedures should have emerged also in this type of establishments, thus entailing a similar assessment and consequently a massive delisting of approved establishments. In our view, this proves that the control level in establishments has not suddenly worsened, but has remained at least on constant levels. Despite the deficiencies that in some cases may have been attributed to the training of official veterinarians, especially on

issues such as own-check and HACCP, it is not possible to claim that the Italian control system is on the whole inadequate.

Meat products	*1999*	*2000*	*2001*
Audited	18	2	19
Acceptable	17	2	9
Marginal	1	0	7
Unacceptable	0	0	3

Therefore, the problem seems to concern mainly slaughterhouses. At this point the fact that there are only 8 slaughterhouses out of 141 establishments certified to export to the US up to May 2001 cannot pass unnoticed. 5 out of these slaughterhouses have been delisted and 3 have been considered as marginal. This means that the exports of meat products to the United States could be completely stopped shortly, even though more than one hundred establishments will still be regularly certified.

This makes us wonder: how can it be that three establishments considered as acceptable in 2000 have suddenly been classed as unacceptable? The past experience in all Countries has always proved that it is highly unlikely for an establishment with adequate standards to become "unsuitable" in the course of a year and vice versa with respect to procedures, above all if these procedures have not changed. Changes (for the better or for the worse) are normally gradual and not sudden. While conceding that a particular situation may have occurred in one establishment, it is quite difficult to believe that a sudden worsening has occurred involving at the same time roughly half of the largest slaughterhouses in the sector.

Moreover, as far as SSOPs and HACCP, it should be noted that we were quite puzzled at the yardstick used for evaluation. Starting from the assumption that – as we have seen- most of the establishments delisted are slaughterhouses, and considering that all the slaughterhouses were audited during each inspection of the FSIS staff, it is clear that the general remarks expressed on HACCP and SSOPs and on their development refer to slaughterhouses. Thus, it is not clear why:

1. SSOPs, which were considered as acceptable in most establishments in 1999 and also in 2000, turned out to be inadequate in many establishment in 2001;
2. HACCP was considered as acceptable in most establishments in 1999, "with deficiencies in most establishments" in 2000, and becomes "unacceptable in many establishments " in 2001.

This is a quite curious development, since food businesses may find difficulties in making a good start with their own-check plans, but normally the situation gradually improves.

It is really hard for us to understand how can it be that the level of Italian pig meat slaughterhouses has worsened so much from the points of view of facilities, hygiene, own-checks, HACCP and SSOPs over a period of only two years, together with the

incapability of control services to remedy the situation, as stated in the report of the US authorities:

"This audit marks what we see as a three-year trend of gradually deteriorating conditions in many meat establishments that the Government of Italy has certified for export to the United States"

Subsequently, a brief analysis of the causes is supplied:

"The recurring theme in FSIS audit findings over the last three years is inadequate central and regional supervision of local government inspection activities in Italian meat establishments. Many of these establishments engage in unsanitary processing practices that routinely result in direct contamination of edible product. We see these issues as inextricably linked."

Inadequacy of the regional and central supervision

This remark has a certain justification with respect to the lack of formal instructions aimed at harmonizing the control and supervision procedures of the local authorities. On the other hand, at the regional level the instructions turned out to have been supplied in a non-homogeneous way, and therefore this does not mean an absolute lack of operative instructions but a certain heterogeneity among the various Regions. In this regard the creation of an interregional working group represents a possible solution to your remarks on this issue.

It should be added that despite the debates and the clarifications supplied during the inspectors' visit there still is a basic misunderstanding on the role that has to be plaid by the control bodies involved at the various levels in the supervisions activities. We report below what has been underlined in this regard in the report:

"...inadequate central and regional supervision of local government inspection activities in Italian meat establishments..."

"Infrequent visits to establishments by the "second-line" supervisor, that is, lack of central or regional supervision over the inspection activities being conducted in the establishments"

"Periodic supervision of inspection visits to establishments performed only once or twice a year (2000 e 2001)"

The Italian system provides for the continuous presence of at least one veterinarian during the slaughter operations. Often in industrial-capacity establishment more than one veterinarian is present at the same time, and they are in any case civil servants. The presence of a high number of auxiliaries, like in the United States and in other Countries, necessarily requires the supervision of the official veterinarian but in our situation it is clear that the monthly supervision activities on the establishment – which is considered as a prerequisite by the US inspectors – has to be carried out by the official veterinarian responsible for the establishment itself. It has to be reiterated that the latter is a civil servant, is officially

appointed and is eligible for such a position only if he has acquired a university degree, a post-university specialization diploma, sufficient experience and if he has passed a state examination and a public competition. As far as the "second level" inspection, in our view this task is up to the head of the Veterinary Service or a person delegated by him, having experience and knowledge sufficient to carry out a verification on the establishment in general, on processing hygiene, on the own-check plan and on the activities of the official veterinarian. A "second level" verification twice a year seems acceptable, considering the high specialization level which is requested from the official veterinarian and considering that the latter carries out a verification every month in all cases.

As to the role of the Regional authorities and of the Ministry, they are in charge of drawing up an annual plan for the general review of establishments processing food of animal origin, but it is clear that they cannot carry out a verification twice a year or even every month.

On the other hand, the Regional Authorities and the Ministry – each according to their own competencies - are in charge of guidance and co-ordination activities, as well as of a periodical supervision based on plans and aimed at verifying the uniform implementation of the provisions in force and of the operative guidance supplied.

The references to the inspections carried out by the FVO inspection staff

In some passages the letter of the US authorities mentions a report published by the European Commission relating to an inspection carried out by the FVO in Italy in October 2000 on the pig meat sector. The goal of it seems clear: supporting the US arguments to reach the conclusion that Italy has a particular situation and represents a "problematic case".

First of all some parts of the quotation are disputable:

"In particular, Commission auditors noted that the Italian central competent authority (CCA) has no legal power over government veterinary activities at regional level"

There is passage of the report where it is stated that this power exists even though it is not exercised directly, but this was not quoted.

"No evidence of pest control"

Actually the text of the FVO report is the following " No evidence of supervision on pest control", and the meaning is substantially different.

"Sterilizers not functioning"

The passage following this one is not quoted, where it is stated that a corrective measure was adopted during the inspection in this regard.

Beyond these details, it has to be underlined that only some passages of the report are quoted. These passages are out of the general context and thus seem to support the remarks of the USDA/FSIS inspectors. But when we run through the whole report, even though some problems to be remedied are underlined, the overall situation which emerges does not appear particularly worrying, especially if it is considered within the wider EU context.

Subsequently, the letter of the US authorities quotes another report concerning an inspection carried out in November 2000 on the sector of minced meat and meat preparations (sanco0/1235/2000-mr final). At first sight it is rather curious that an inspection carried out on a sector which is not involved in the exports to the United States was taken into consideration, but the aim of this is better understood when we read the final conclusions.

"The conclusion we reach from our last three audits—combined with correlation findings by the European Commission—is that Italy is on the brink of a meat inspection system failure".

Practically a report drawn up by the European Union inspectors on a sector which is not involved in the export to the United States is used to justify the statement according to which "Italy is on the brink of a meat inspection system failure".

This statement is a really serious one and is certainly not supported by the findings of the FVO mission in the specific pig meat sector.

Similar situations of difficulty of the veterinary activities emerged from the report of the inspection carried out by the FVO inspectors in the U.S.A. in June 2000, which specifically concerned the supervision on cold stores and the certification of fresh meat, and whose remarks completely match those mentioned above. In this regard some specific conclusions on the supervision system are significant:

- There is no continuous veterinary supervision and this supervision can be carried out by non-veterinary staff;
- Lack of evidence of veterinary checks;
- The controls and supervision are not uniform and vary according to districts;
- The frequency of supervision is not established but depends on the supervisor.

Also in this case the FVO inspectors detected non-conformities which were never mentioned by the US system (including the presence of condensation water!), as well as the presence of some establishments which are not complying with the provisions in force.

We also discovered that many goods coming from the United States were rejected due to irregular certificates, and in fact the US authorities were invited to draw up a paper clarifying the tasks of the veterinarian, and especially the need for him to be

aware of the contents of the certificate and substantially of what he signs. At any rate, the inspection established that the certification procedures are not reliable.

Considering the restricted scope of the inspection, the remarks made seem important in for the safety of EU consumers.

SPECIFICATIONS ON THE 2001 FSIS USDA REPORT

1) According to the findings of the audits carried out by the two inspection teams the criteria for assessing the establishments appear to be dissimilar. In particular, inspection team A has a more severe approach compared with team B; moreover, it was requested to delist establishments which had a situation substantially similar to other establishments maintained on the list even though considered as marginal.
2) Moreover, we observed a certain tendency to generalize the remarks: the inspectors detected a presence of fat traces on 2-3% of containers examined and the relevant remark is generalized to "containers coming into direct contact with the foodstuffs "; if the temperature of a sterilizer is 78°C-80°C whereas the other 10 or 15 sterilizers are above the fixed temperature of 82°C, it is stated that "the sterilizers are not maintained at the correct temperature ". It is clear that each remark has to be assigned an importance that varies according to different criteria, first of all any possible consequence that the deficiency may have on food safety. Otherwise, one runs the risk of putting completely different situations on the same level, and problems which certainly have to be remedied but which provide at any rate guarantees on food safety may thus appear as shocking.
3) The table reported on page 1 of the report for the year 2001 indicates nine acceptable establishments and ten marginal establishments, as reiterated on the table in appendix A: in this regard it should be noted that establishment 172/L UNIBON - REGGIO EMILIA is indicated as marginal, re-rewiev on the table in appendix A; actually on the final tables relating to the single establishments it is indicated as acceptable and in attachments A (SSOP) and B (HACCP) all the items taken into consideration are considered favorable. This overall evaluation seemingly confirms the evaluation on the eligibility of establishment 172/L for export to the United States made by the official veterinarian of the Emilia Romagna Region, Dr Marco Pieraruoni, on the day of the inspection.
4) RESULTS AND DISCUSSION - PART 2 RECORD REVIEW - Inspection System Controls:
The first point considers as a deficiency what is actually the feature of the control system in place in our Country, in fact, it is stated that the official veterinarian is present only occasionally in 13 establishments, without taking into account the fact that the ongoing presence of the official veterinarian is

mandatory only in slaughterhouses during the slaughter operations. This remark is a new one, and is very important also in consideration of the stress laid on it in the following part of the report, without considering that the EU provisions do not provide for the daily presence of the official veterinarian in processing establishments; in the specific case of hams processing plants curing is the prevalent activity that don't reach products handling while the salting of the products is only done periodically.
the second point underlines a misunderstanding as to the authority in charge of the monthly supervisory visits, that according to the ministerial instructions should be the Head of the Veterinary service of the Local Health Unit or his representative, and not the Regional authorities.

5) RESULTS AND DISCUSSION - PART 3 - ON SITE ESTABLISHMENT AUDITS SANITATION CONTROL - cross contamination :
(in 13 establishments, dripping condensate...) actually the formation of condensation, mainly in coolers for cut meat, in slaughterhouses performing heat-cutting, represents a real problem which the various establishments have tried to solve for some time without obtaining the desired results; however it should be noted that in several cases the inspector has overestimated the importance of the inconvenience;
(in five establishment, the automatic offal....) the stress laid on certain blood or fat residues which remain on the trays for transporting offal after washing seems excessive, since abdominal viscera aren't normally intended for consumption, and therefore aren't used as casings for sausages.

6) RESULTS AND DISCUSSION - PART 3 - ON SITE ESTABLISHMENT AUDITS - ANIMAL DISEASE CONTROL
(in seven establishments.....) in this audit the way of handling processing waste is disputed, contrary to what happened in the previous audits:
the UE legislation provide for the identification of materials not fit for human use as pathological material that must be segregate in inviolable container.
On the other hand, when materials fit for human consumption are to be used for animal husbandry on the basis of the company's choice, it is not necessary to color or denature them or to identify containers.
The only thing necessary is a contract with a specialized company which withdraws the material in question and subjects it to further treatment. All the containers inside the establishment were made of materials fit for coming into contact with foodstuffs, regardless of their use; such containers are washed, cleansed and disinfected each time before use;

7) RESULTS AND DISCUSSION - PART 3 - ON SITE ESTABLISHMENT AUDITS *Listeria monocytogenes* testing:
Listeria monocytogenes testing programs had never been requested before; following the request of the USDA inspector the establishments included on the US list were requested to add such a testing to their own-check procedures.

REMARKS ON THE ESTABLISHMENTS

304 M/S - MEC CARNI SPA - MARCARIA (MN)

1) The inspection form relating to this establishment contains some mistakes: the inspectors has stated that Dr Pierantoni of the Emilia Romagna Region assisted to the inspection, instead of Dr. Castoldi of the Lombardia Region;
2) The temperatures of sterilizers were recorded by a thermometer of the establishment whose calibration had not been previously checked by the inspector;
3) The presence of mould on the ceiling of the slaughter area only concerned an area of few square centimeters;
4) The meat or fat residues on the surfaces of the steel containers intended to contain the meat were only two small pieces of meat and fat whose sizes were smaller than one centimeter, out of forty steel containers carefully examined by means of a torch;
5) The insufficient cleaning of the lower surfaces of working tables, which are not intended to come into contact with meat, do not necessarily entail the direct or indirect contamination of meat, of equipment or of the hands of operators;
6) The cold room where condensation was detected was turned off and empty;
7) The request for an immediate interruption of slaughtering after the temperature of some sterilizers was found to be lower than foreseen cannot concern the animals already killed; otherwise, waiting to restore the proper functioning of sterilizers, it would be necessary to maintain those carcasses not completely processed on the slaughter chain;
8) The supervision by the veterinarian entrusted to do that by the head of the veterinary service is carried out monthly, as evidenced by the inspection reports.

92 M/S - FUMAGALLI INDUSTRIA ALIMENTARE SPA - TAVERNERIO (CO)

1) Only two knife sterilizers out of five had a water temperature lower than +80°C, the values recorded on the three other sterilizers were respectively: +80°C, +81°C, +85°C; in this regard it has to be observed that the thermometer used to record water temperature had a measurement reliability of +/- 1°C; for all the sterilizers the displays showed temperatures higher than +83°C and this is why the non-conformity was not noted by the person in charge of the own-check plan; moreover, the sterilizers and their control board were completely replaced after the FSIS inspectors' audit in Fall 2000;

2) The rust found on some facilities did not concern any of the surfaces intended to come into direct or indirect contact with meat; in one case it was a disused catenary curve in the heat-boning area.
3) All the containers inside the establishment were made of materials fit for coming into contact with foodstuffs, regardless of their use; such containers are washed, cleansed and disinfected each time before use;
4) The presence of dirt on the ceiling of the cold curing room only consisted of a small piece of fat, whose size was approximately 1 cm, probably pushed onto the ceiling during the cleaning operations carried out with high-pressure equipment;
5) During the 2000 audit the risk analysis carried out by the establishment management within its own HACCP plan was judged acceptable; this same analysis has been considered unacceptable during the 2001 audit;
6) In comparison with the findings of the 2000 audit, the establishment has introduced and implemented pre-shipment document review procedures judged appropriate by the FSIS inspector ;
7) During the 2000 audit the methods for recording data relating to *E. coli* testing were judged acceptable; these same methods have been judged unacceptable during the 2001 audit;
8) The establishment was audited in 1999 and 2000 and in both cases it was judged suitable;
9) Dr Gridavilla, Dr Noè and Dr Castoldi took note of the final assessment of the FSIS inspector but did not agree on it; in fact, had they deemed the deficiencies noted such as to jeopardize the approval of the establishment under Directive 64/433/EEC they would have proposed to suspend it;
10) The Veterinary service of the Como Local Health Unit supplied detailed information on the corrective measures taken by letter of 1st June 2001 n. 2251.

643/M/S - F.LLI MARTELLI SPA - DOSOLO (MN)

1) The unacceptable assessment attributed to this establishment was not shared by the regional officer and by the ministerial officer present, nor by the LHU supervisor of the establishment; such a position was also expressed by means of the interpreter during the final discussion held in the establishment: in their view the deficiencies noted compromised neither the compliance of the establishment with the EU provisions nor the hygiene conditions of meat production. On the other hand they agreed upon the need to take corrective measures, which were promptly adopted, as communicated by the Mantova Local Health Unit by letter n. 3788 of 31st May 2001;

2) As far as the single remarks are concerned, we would like to make clear that the establishment has verified and replaced those sterilizers whose water level was insufficient to sanitize the whole blade of knives;
3) A light was installed in the hog head inspection station in order to improve the lighting conditions;
4) As far as the presence of some dripping condensate, which was only noted at the entrance of the freezing room for fat pieces coming for the heat-cutting area and transported by automatic rails , artificial ventilation equipment was installed to reduce the occurrence of this inconvenience combined with frequent cleaning of the freezing room;
5) The presence of traces of mineral fat, of grease and of small meat pieces was noted especially under the tables, on the hook pulleys, under the conveyor belts and generally, with two exceptions, on surfaces which are not intended to come into direct contact with meat; the aprons were worn out only in rare cases and mineral fat residues were actually found only on the apron of one of the employees in charge of removing the hooks, who did not directly handle the meat; instructions were given to prevent re-occurence of these inconveniences;
6) As far as the presence of a residue of meat, of a fat pieces and of dirt on the floor of the freezing room for fat pieces, daily cleaning and verification operations have been envisaged;
7) Corrective instructions were given to the employee in charge of removing the hooks in the cutting area who had laid his gloves on a board and took them back later, and to the employee who had moved a container intended for cutting waste without washing his hands before resuming work;
8) The cooling water hose of the carcass splitting saw contacting hog carcasses was re-positioned by an adequate hole in the platform;
9) the meat which had come into contact with the floor in the cutting area when moved has been withheld and subjected to trimming of the part concerned; the procedure for adopting corrective measures was adjusted according to the instructions supplied by the USDA inspector;
10) the forms for the verification of any deficiency noted during the implementation of the SSOP procedures were reviewed by the establishment management, in order to make them more detailed and tailored to the features of the establishment itself;
11) the containers for products unfit for human consumption have been properly identified; in case of need these same containers may also be placed in the cutting room after the appropriate cleaning and disinfecting operations;
12) HACCP plan: difficulties have emerged in interpreting the papers drawn up by the establishments, as regards the plan design and the forms for verifying the CCPs identified, any non-conformity detected and the corrective measures put in place. The HACCP plan was reviewed by the establishment and was separated from the SSOP plan, as requested by the USDA inspector;

13) By letter n. 3788 of 31st May 2001 the Veterinary Service of the Mantova LHU supplied detailed information on the corrective measures adopted.

1597/L - ANCONA CARNI SRL - ANCONA (AN)

1) The fat residues – which are very small-sized – found on the ham working table only concerned surfaces which do not come into direct contact with foodstuffs, that is the table legs and the lower part of the plane;
2) As far as label approval, the US inspector had been told that during the audit no approved label would be available, since the establishment in question had not yet exported any product to the United States;
3) As to the compliance of the establishment with the basic requirements of the HACCP system, the official veterinarian in charge of the establishment communicated (letter ref. n. 26646 of 30 May 2001) that the corrections and the supplements requested have been carried out;
4) The unfavorable outcome of the audit was not notified to the establishment at the end of the inspection; the establishment management had understood that once the own-check plan had been corrected and the deficiencies remedied, exports could have started.
5) The Veterinary Service of the Ancona LHU supplied detailed information on the corrective measures adopted by a letter on 30 May 2001.

768/M/S - INDUSTRIE RIUNITE CAMPAGNOLO SPA - CANDIOLO (TO)

1) During the audit a thoracic offal (out of hundreds of them which transited before the inspection team) fell into the gutter before veterinary inspection. The operator, without following the instructions given to him, did not hang it back. Therefore, the carcass reached the inspection site without such an offal and was sent to the room for retained products and then set apart. In sum, the offal was not actually recovered, an actual problem has occurred, but it only concerned one pig whose carcass was declared as unfit for human consumption and retained. Therefore, in our view it is not possible to consider this deficiency as evidence of the inadequate inspection standards of the Veterinary Service. The fact that a similar inconvenience is unusual is demonstrated by the absence of any other offal in the gutter, despite the fact that roughly a thousand pigs had already been slaughtered.
2) As to the presence of condensation, the situation on the whole has improved, even though the problem has not been completely solved. The meat could be directly contaminated only in the room for retained meat, even though no liquid dripping directly on the meat was noted. In the other premises the meat is stored in such a way as to make it impossible to place it in areas where

condensation may develop. It should be noted that practically all the rooms where carefully inspected. Last year condensation had also been found in the cutting room, besides the chilling rooms.

3) Dirty containers and tables: it has to be noted that a high number of containers were inspected, and also that only on a very low number of these containers traces of organic material were found, and at any rate only on containers where the meat is stored after being wrapped with a plastic sheet, thus avoiding any direct contact. No traces of dirt were found on the surfaces of tables, but only on the lower parts in some cases.
4) A half-carcass accidentally fell during cutting, and one of the operators in charge of managing non-conformities did not wash his hands before resuming work, contrary to what the others did. The operator avowed he did not think it necessary to wash his hands, even in the presence of the inspector, since he had used a clean hook and therefore he had not touched the half-carcass by his hands, and he had to take immediate action in order to prevent a similar inconvenience from re-occurring. It has to be underlined that the half-carcass was at any rate set apart for further treatment. During an inspection in the United States carried out in the year 2000 the FVO inspectors noted that in an establishment the corrective measures envisaged by the SSOP procedures for pig meat falling on the floor consisted in washing meat with potable water; such a procedure had not been disputed during routine checks.
5) HACCP and own-checks: During the audit there have certainly been misunderstandings as to the term "critical limit ", but then sight of the fundamental point was lost: the attainment of the goal, that is zero fecal contamination. What was defined by the establishment as critical limit is maybe something different, an attention threshold, but what counts is that establishment achieved the goal.
6) At the time of the audit, no conditions susceptible of presenting risks for human health were noted in establishment 768MS.
7) By examining the remarks made last year, the solutions adopted and the remarks made during the last audit, it can be noticed that the problems emerged in the 2000 audit were remedied (and therefore solutions were adopted). Therefore it is not possible to state that the problems are always the same, nor that the establishment and the Veterinary Service did not implement the measures requested. Moreover, the statement according to which the situation has gotten worse is questionable.
8) No visible fecal contamination was found on carcasses; therefore, the system put in place by the establishment has to be considered as effective.
9) The Carignano Local Health Unit n. 8 supplied detailed information of the corrective measures adopted by a letter of 1st June 2001.

272 M/S/L - CESARE FIORUCCI SPA - SANTA PALOMBA (RM)

1) By letter n. 1398 of 1st June 2001 the veterinary service of the Rome-H LHU communicated that the deficiencies observed by the US inspectors had been remedied, and a detailed report of all the corrective measures taken was attached.

989/L CORTE BUONA SPA - PALIANO (FR)

1) The establishment supplied detailed information on the corrective measures adopted by a letter of 25 May 2001.

2. Audit on laboratories

1. Lazio and Toscana Experimental Zooprophylactic Institute (IZS)

Food Microbiology Laboratory (Rome)

a) *Salmonella:* The procedures used by the IZSLT for *Salmonella* testing comply with the methods recognized by international standards (ISO 6579/93) and are accredited by SINAL.

b) *Listeria monocytogenes:* 2 different methods are used, and both are accredited by SINAL.
   1) the method foreseen by OM 7.12.93 (Official Journal n.291 of 13-12-1993" Limits of *Listeria monocytogenes* in certain foodstuffs ") for foodstuffs to be consumed after cooking, since the Italian legislation not only provides for the search and identification of the germ but also for the quantification of the number of *L.monocytogenes* present (quantitative);
   2) the method UNI EN ISO 11290/1/97 for the other foodstuffs (qualitative method, indicating only the presence or absence of *L.monocytogenes* in tested products).

c) Generic *E.coli*: the method used is accredited by SINAL and validated by AFNOR (French Normalization Association).
Such a reference was available at the laboratory but was neither requested nor examined by the inspector.

d) *Sample verification program*: the IZSLT food microbiology laboratories take part in multi-laboratory essays (QM and Senate). Considering that the outcome of these multi-laboratory tests has constantly been satisfactory for *Salmonella and Listeria* testing, and evidence thereof exists up to 1999, the Institute decided to take part in these multi-lab tests also for other pathogenic germs based on a rotation program.

According to such a program, *Salmonella and Listeria* testing are scheduled in next October.

Moreover, it should be noted that the Institute joined the experimentation requested by the Ministry of Health of the Pilot Plan on *Salmonella and E.coli* testing on pig carcasses by means of sponge samples collected by the competent LHU Veterinary Services in slaughterhouses approved for export to the United States (Circular Letter of the Ministry of Health ref. 600.3/SP.31/6885 of 23 October 1998 and Circular letter of the Ministry of Health ref. 600.3/SP.31/7592 of 24 November 1998).
Such tests were carried out in order to compare the ISO 6579/-93 method and the AOAC 967.25/95 method for *Salmonella* and the ISO 7251/93 method and the AOAC 991.14/95 method for *E.coli*. (Circular Letter of the Ministry of Health ref. 600.3/SP.31/8233 of 29 December 1998).
The results of the Pilot Plan for *E.coli* testing on pig carcasses are reported in Circular Letter of the Ministry of Health ref. 600.3/SP.31/5578 of 14 September 1999.
Subsequently we never received any specific communication on the sampling methods and frequency and on the analytical methods to be used for foodstuffs to be exported to the United States.

Food Microbiology Laboratory (Florence)

The same goes for the remarks made by the inspector at the Florence laboratory concerning the procedures used for *Salmonella, Listeria monocytogenes and E.coli* testing, sample quantity and sample verification program.
As far as the remark on the use of plates divided in half, such a method is based on a requirement which preceded the procedure in use at the time of the audit. This non-compliance, which is at any rate exclusively formal and not substantial, was promptly solved by inviting all the operators to comply strictly with the procedures in use.

2. Umbria and Marche Experimental Zooprophylactic Institute:

Food Microbiology Laboratory of Ancona and Perugia

a) *Salmonella:* both the screening methods used in the two laboratories were validated respectively by AOAC and AFNOR. With regard to the confirmation method, both laboratories use the same method (PG MICALI PRT 007 rev. 004) accredited by SINAL.
Salmonella testing on carcasses by sponge sampling was never asked for by the official sampling bodies and therefore never carried out in our laboratories.

b) *Listeria:* the screening method used in the Perugia Microbiology Laboratory was validated by AFNOR.
Also the culture method used by both laboratories (PGMICALI PRT 007 rev. 003) has been accredited by SINAL.

c) Generic *E.coli*: the method used in both laboratories (AN MICALI PRT002

rev. 004) was not only accredited by SINAL but is also an Italian standard method (draft norm UNI U 59003300 – September 2000) and is also internationally recognized by AOAC (BAM Edition VIII of 1998).

All the mentioned procedures constantly undergo external quality controls, by way of attendance at national and international multi-laboratory circuits; evidence thereof has been carefully examined by the FSIS inspector.

3. Emilia-Romagna Experimental Zooprophylactic Institute

Food Microbiology Laboratory of Brescia

a) *Salmonella* and *Listeria monocytogenes*: The research methods for *Salmonella* and *Listeria monocytogenes* are accredited by SINAL.
The validation of these methods was carried out (following a General Procedure establishing minimum validation criteria for microbiological methods) by a multi-laboratory essay but also by a comparison with a "Gold Standard" reference method (ISO 6579/93- ISO 11290-1/96). The results of the above mentioned tests haven't been viewed by the inspector even if available at the laboratory.
The review of the above-mentioned methods foresees the inclusion of the validation parameters obtained from the referenced tests.

b) *Escherichia coli*: The general method for *E. coli* testing is accredited by SINAL. This method - still in rev. 0 - has been tested many times in inter-laboratory circuits, even though not in recent periods. The review will include the precision parameters of repeatability at three different contamination levels. It will be also specified how to assess the results obtained in the course of time. The results of the above mentioned tests haven't been examined by the inspector even if available at the laboratory.

4 Experimental Zooprophylactic Institute of Piemonte, Liguria and Valle d'Aosta

Food Control Laboratory of Turin

The methods used for *Salmonella*, *L. monocytogenes* and *E. coli* testing are accredited by SINAL.

a) *Salmonella* (ANFOR V08-052, 1997): The method is validated by ANFOR (French Normalization Association) and refers to the EU norm EN ISO 6579/1993.

b) *Listeria monocytogenes* (ANFOR V08-055, 1997): Validated ANFOR, it refers to the EU norm EN ISO 11290-1/1996.

c) *E. coli*: we apply the proposed ISO/TC/34/SC9/N330-1998, which became a EU norm after the approval of the ISO Commission (ISO/FDIS16649-2/2000): the reliability limits are indicated by ISO7218/1996.

All the references quoted for Salmonella, *Listeria monocytogenes* and *E. coli* relating to the acceptability of laboratory methods, have been neither asked for nor checked by the inspector.

Moreover, it should be noted that our laboratory took part in the experimentation of the Pilot Plan requested by the Ministry of Health for *Salmonella* and *E.coli* testing on sponge samples from pig carcasses taken in slaughterhouses certified for export to USA by the LHU Veterinary Services (Circular letter of the Ministry of Health 600.3/SP.31/7592 of 24 November 1998).
This experimentation was carried out in collaboration with other Experimental Zooprophylactic Institutes (IZS of Lazio and Toscana, IZS of Lombardia and Emilia Romagna and IZS of Abruzzo and Molise).
The aim of this research was comparing the method ISO 6579/93 with the method AOAC 967.25/95 used for *Salmonella* testing and the method ISO 7251/93 with the method AOAC 991.14/95 used for *E. coli* testing (Circular letter of the Ministry of Health 600.3/sp.31/8233 of 29 December 1998).
We never received subsequently any specific notice on the sampling methods and frequency, neither on the analytic method to be used for foodstuffs intended for export to the USA.

Chemistry Department- Chemistry and Bromatology laboratory

The search for polychlorinated byphenyls in tissues is carried out by mass gaschromatography/fragmentography (GC/MS/SIR) after sample purification by dimensional exclusion chromatography (HPCL-SEC). At the moment the percent of recovery is not verified by addition of congeneri 3C12-marked; for every analysis batch, it is normally evaluated on PCBs-free real sample added with markers congeneri. The real data obtained on organic matrix (homogenized meat) report minimum recovery values of 68%, (congenere PCB-101) and maximum recovery values of 140%, (congenere PCB-138) at an added level of 20 ng/g lipidic basis (intercalibration 05/2000).
Considering the complexity and type of analyzable matrixes (muscular tissue and by-products, fat tissue, egg, milk, and by-products) as well as the little concentration to be noted , it is possible to obtain lower percents of recovery compared to those observed the inspection visit.

The laboratory will have to improve the dosage performances to re-enter in the acceptability range indicated by the inspectors.
As to the quantity of sample to be submitted to *Salmonella* testing, waiting for a clarification from the US authorities, we inform you that the IZS of Umbria and Marche does not performs any analysis on behalf of Italian slaughterhouses approved for export but only for slaughterhouses located in the Republic of San Marino.

5. National Health Institute

The ISO references of methods corresponding to UNI methods used by the NHI for *Salmonella* testing and *E. coli* enumeration delivered to the USDA inspectors during their visit to the laboratory, are ISO/DIS 6579 - Microbiology of food and animal feeding stuff- Horizontal method for detection of salmonella spp doc ISO/TC34/SC9N 454 rev 1st April 2001 and ISO/WD 16649-3 Horizontal method for the enumeration of beta glucuronidase positive *Escherichia coli*- part 3: Most probable number technique doc ISO/TC 34/SC 9 N499 April 2001.